

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended March 31, 2020

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 001-38599

**Aquestive Therapeutics, Inc.**

(Exact Name of Registrant as Specified in its Charter)

Delaware

(State or other jurisdiction of Incorporation or organization)

30 Technology Drive, Warren, NJ 07059  
(908) 941-1900

(Address, Zip Code and Telephone Number of Registrant's Principal Executive Offices)

82-3827296

(I.R.S. Employer Identification Number)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.001 per share	AQST	NASDAQ Global Market

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.  Yes  No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).  Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer", "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Securities Exchange Act of 1934.

Large accelerated filer   
Non-accelerated filer

Accelerated filer   
Smaller reporting company   
Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).  Yes  No

The number of outstanding shares of the registrant's common stock, par value \$0.001 per share, as of the close of business on May 1, 2020 was 33,582,696.

**AQUESTIVE THERAPEUTICS, INC.**  
**QUARTERLY REPORT ON FORM 10-Q**  
**FOR THE QUARTER ENDED MARCH 31, 2019**  
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**PART I – FINANCIAL INFORMATION****Item 1. FINANCIAL STATEMENTS (Unaudited)**

**AQUESTIVE THERAPEUTICS, INC.**  
Condensed Consolidated Balance Sheets  
(In thousands, except share and per share amounts)  
(Unaudited)

	<u>March 31,</u> <u>2020</u>	<u>December 31,</u> <u>2019</u>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 35,521	\$ 49,326
Trade and other receivables, net	9,536	13,130
Inventories, net	3,087	2,859
Prepaid expenses and other current assets	2,944	2,999
<b>Total current assets</b>	<b>51,088</b>	<b>68,314</b>
Property and equipment, net	9,059	9,726
Right-of-use assets, net	3,912	—
Intangible assets, net and other assets	428	439
<b>Total assets</b>	<b>\$ 64,487</b>	<b>\$ 78,479</b>
<b>Liabilities and stockholders' deficit</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 14,090	\$ 17,749
Lease liabilities, current	609	—
Deferred revenue, current	663	806
<b>Total current liabilities</b>	<b>15,362</b>	<b>18,555</b>
Loans payable, net	60,922	60,338
Lease liabilities	3,424	—
Deferred revenue, net of current portion	4,209	4,348
Asset retirement obligations	1,399	1,360
<b>Total liabilities</b>	<b>85,316</b>	<b>84,601</b>
<b>Contingencies (note 18)</b>		
Stockholders' deficit:		
Common stock, \$.001 par value. Authorized 250,000,000 shares; 33,582,696 and 33,562,885 shares issued and outstanding at March 31, 2020 and December 31, 2019, respectively	34	34
Additional paid-in capital	126,141	124,318
Accumulated deficit	(147,004)	(130,474)
<b>Total stockholders' deficit</b>	<b>(20,829)</b>	<b>(6,122)</b>
<b>Total liabilities and stockholders' deficit</b>	<b>\$ 64,487</b>	<b>\$ 78,479</b>

See accompanying notes to the condensed consolidated financial statements.

**AQUESTIVE THERAPEUTICS, INC.**  
Condensed Consolidated Statements of Operations and Comprehensive Loss  
(In thousands, except share and per share data amounts)  
(Unaudited)

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2020</b>	<b>2019</b>
Revenues	\$ 8,765	\$ 12,643
Costs and expenses:		
Manufacture and supply	3,659	3,506
Research and development	4,354	4,303
Selling, general and administrative	14,613	17,908
Total costs and expenses	<u>22,626</u>	<u>25,717</u>
Loss from operations	(13,861)	(13,074)
Other income/(expenses):		
Interest expense	(2,771)	(1,926)
Interest income	102	274
Net loss before income taxes	(16,530)	(14,726)
Income taxes	—	—
Net loss	<u>\$ (16,530)</u>	<u>\$ (14,726)</u>
Comprehensive loss	<u>\$ (16,530)</u>	<u>\$ (14,726)</u>
Net loss per share - basic and diluted	<u>\$ (0.49)</u>	<u>\$ (0.59)</u>
Weighted-average number of common shares outstanding - basic and diluted	<u>33,569,694</u>	<u>24,963,603</u>

See accompanying notes to the condensed consolidated financial statements.

**AQUESTIVE THERAPEUTICS, INC.**  
Condensed Consolidated Statements of Changes in Stockholders' Deficit  
(In thousands, except share amounts)  
(Unaudited)

	<u>Common Stock</u> <u>Shares</u>	<u>Amount</u>	<u>Additional</u> <u>Paid-in</u> <u>Capital</u>	<u>Accumulated</u> <u>Deficit</u>	<u>Total</u> <u>Stockholders'</u> <u>Deficit/Equity</u>
Balance December 31, 2019	33,562,885	\$ 34	\$ 124,318	\$ (130,474)	\$ (6,122)
Share-based compensation	19,811	—	1,823	—	1,823
Net loss	—	—	—	(16,530)	(16,530)
Balance, March 31, 2020	<u>33,582,696</u>	<u>\$ 34</u>	<u>\$ 126,141</u>	<u>\$ (147,004)</u>	<u>\$ (20,829)</u>
Balance December 31, 2018	24,957,309	\$ 25	\$ 71,431	\$ (61,376)	\$ 10,080
Adoption of ASU 2014-09 and ASU 2018-07	—	—	20	(2,852)	(2,832)
Share-based compensation	17,830	—	1,422	—	1,422
Net loss	—	—	—	(14,726)	(14,726)
Balance, March 31, 2019	<u>24,975,139</u>	<u>\$ 25</u>	<u>\$ 72,873</u>	<u>\$ (78,954)</u>	<u>\$ (6,056)</u>

See accompanying notes to the condensed consolidated financial statements

**AQUESTIVE THERAPEUTICS, INC.**  
Condensed Consolidated Statements of Cash Flows  
(In thousands)  
(Unaudited)

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2020</b>	<b>2019</b>
Cash flows from operating activities:		
Net loss	\$ (16,530)	\$ (14,726)
Adjustments to reconcile net loss to net cash used for operating activities:		
Depreciation and amortization	887	783
Share-based compensation	1,860	1,520
Amortization of debt issuance costs and discounts	584	389
Non-cash interest expense	-	527
All other non-cash expenses	(144)	(45)
Changes in operating assets and liabilities:		
Trade receivables and other receivables	3,738	(963)
Inventories, net	(228)	304
Prepaid expenses and other current assets	53	(1,715)
Accounts payable and accrued expenses	(3,575)	(3,306)
Deferred revenue	(282)	(448)
Net cash used for operating activities	<u>(13,637)</u>	<u>(17,680)</u>
Cash flows from investing activities:		
Capital expenditures	(131)	(376)
Net cash used for investing activities	<u>(131)</u>	<u>(376)</u>
Cash flows used for financing activities:		
Payments for taxes on share-based compensation	(37)	(2,609)
Net cash used for financing activities	<u>(37)</u>	<u>(2,609)</u>
Net decrease in cash and cash equivalents	(13,805)	(20,665)
Cash and cash equivalents:		
Beginning of period	49,326	60,599
End of period	<u>\$ 35,521</u>	<u>\$ 39,934</u>
Supplemental disclosures of cash flow information:		
Cash payments for interest	\$ 2,188	\$ 1,009
Net (decrease) in accrued capital expenditures	(84)	(253)
Net increase in financing costs included in accounts payable and accrued expenses	-	311
Accrued withholding tax for share based compensation	(1)	(4)

See accompanying notes to the condensed consolidated financial statements.

**AQUESTIVE THERAPEUTICS, INC.**

Notes to Condensed Consolidated Financial Statements  
(Unaudited, in thousands, except share and per share information)

**Note 1. Corporate Organization and Company Overview****(A) Company Overview**

Aquestive Therapeutics, Inc. (“Aquestive” or the “Company”) is a pharmaceutical company focused on identifying, developing and commercializing differentiated products to address unmet medical needs and solve critical healthcare challenges. The Company has a commercial proprietary product pipeline focused on the treatment of diseases of the central nervous system, or CNS, and is developing orally administered complex molecules as alternatives to more invasive therapies. Aquestive is pursuing its business objectives through both in-licensing and out-licensing arrangements, as well as the commercialization of its own products. Production facilities are located in Portage, Indiana, and corporate headquarters, sales and commercialization operations and primary research laboratory facilities are based in Warren, New Jersey. The Company’s major customer and primary commercialization licensee has global operations headquartered in the United Kingdom with principal operations in the United States; other customers are principally located in the United States.

Aquestive is subject to risks common to companies in similar industries and stages of development, including, but not limited to, competition from larger companies, reliance on revenue from a limited number of products and customers, adequacy of existing and availability of additional operating and growth capital as and when required, uncertainty of regulatory approval for marketing its product candidates, reliance on a single manufacturing site, new technological innovations, dependence on key personnel, reliance on third-party service providers and sole source suppliers, dependence on patent-protected proprietary technology, ongoing government regulatory compliance requirements, dependence on the clinical and commercial success of its drug candidates, and uncertainty of broad adoption of its approved products, if any, by physicians and consumers. Aquestive is also subject to the risks and uncertainties associated with the COVID-19 pandemic. See Note 4. Risks and Uncertainties for further discussion related to COVID-19.

**(B) Equity Transaction***Equity Offering of Common Stock*

On December 17, 2019, Aquestive received net proceeds of \$37,835 after deducting underwriting discounts of \$2,415 for the sale of 8,050,000 shares of common stock in a public offering. Professional fees and other costs of this offering totaled \$540, in addition to the underwriting discounts.

**Note 2. Basis of Presentation**

The accompanying interim unaudited condensed consolidated financial statements were prepared in conformity with U.S. generally accepted accounting principles (“U.S. GAAP”) and with Article 10 of Regulation S-X for interim financial reporting. In compliance with those rules, certain information and footnote disclosures normally included in annual consolidated financial statements prepared in accordance with U.S. GAAP have been condensed or omitted. These condensed consolidated financial statements should be read in conjunction with the Company’s audited consolidated financial statements and related notes for the fiscal year ended December 31, 2019 included in our Annual Report on Form 10-K filed with the SEC on March 11, 2020 (the “2019 Annual Report on Form 10-K”). As included herein, the condensed consolidated balance sheet at December 31, 2019 is derived from the audited consolidated financial statements as of that date. In the opinion of management, all adjustments (consisting only of normal recurring adjustments) considered necessary for a fair statement of the results of interim periods have been included. The Company has evaluated subsequent events for disclosure through the date of issuance of the accompanying unaudited condensed financial statements.

Any reference in these notes to applicable guidance refers to the authoritative U.S. GAAP as found in the Accounting Standards Codification (“ASC”) and Accounting Standards Updates (“ASU”) of the Financial Accounting Standards Board (“FASB”).

**Note 3. Summary of Significant Accounting Policies****(A) Principles of Consolidation**

The interim condensed consolidated financial statements presented herein include the accounts of Aquestive Therapeutics, Inc. and its wholly owned subsidiary, MonoSol Rx, Inc. Other than corporate formation activities, MonoSol Rx, Inc. has conducted no commercial, developmental or operational activities and has no customers or vendors. The results of operations and cash flows reported in these condensed consolidated financial statements should not be regarded as necessarily indicative of results that may be expected in any other interim period or for the entire fiscal year.

## **(B) Use of Estimates**

The preparation of financial statements in conformity with U.S. GAAP requires the use of estimates and assumptions that affect the reported amounts of assets and liabilities, including disclosure of contingent assets and contingent liabilities, at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. Significant items subject to estimates and assumptions include allowances for rebates from proprietary product sales, the allowance for sales returns, the useful lives of fixed assets, valuation of share-based compensation and contingencies.

## **(C) Recent Accounting Pronouncements**

As an emerging growth company, the Company has elected to take advantage of the extended transition period afforded by the Jumpstart Our Business Startups Act for the implementation of new or revised accounting standards and, as a result, the Company will comply with new or revised accounting standards no later than the relevant dates on which adoption of such standards is required for emerging growth companies. The Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on its financial position or results of operations upon adoption.

### *Recently Adopted Accounting Pronouncements:*

In February 2016, the Financial Accounting Standards Board issued ASU 2016-02, *Leases (Topic 842)*, and issued amendments in July 2018 provided by ASU 2018-10. This ASU, as amended, requires lessees to recognize lease assets, termed “right-of-use assets” and related lease liabilities on the balance sheet that had previously been classified as operating leases under prior authoritative guidance. For income statement purposes, leases are now required to be classified as either operating or financing leases under a dual model similar to that specified by ASC 840. Operating leases continue to result in straight-line expense while financing leases result in a front-loaded expense pattern in a manner similar to recognition of capital lease expenses under ASC 840.

The Company adopted ASU 2016-02 on January 1, 2020 using the modified retrospective transition provisions of ASC 842 to leases in effect as of that date of adoption, and recorded lease liabilities and right-of-use assets, as adjusted for accrued lease payments, in the amount of \$4,224 based on an estimated incremental borrowing rate of 16.9%, representing the present value of remaining minimum lease payments. The assets and liabilities thus recorded were primarily those related to the Company’s leased plant, laboratory and corporate administrative facilities. The Company elected to apply the ASU-specified practical expedients and accordingly did not re-assess (i) whether its contracts contained a lease under the new definition of a lease, (ii) the classification of those leases and (iii) initial direct costs of existing leases. In addition, the Company elected not to apply the hindsight expedient in the assessment of lease renewals and resultant term of leases. The Company also elected not to recognize a right-of-use asset and lease liability for those leases with a remaining lease term of 12 months or less. The adoption of ASU 2016-02 did not require a cumulative-effect adjustment to the opening balance of the accumulated deficit at the time of adoption.

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers*, and subsequently amended the standard in ASC 606 which provides a single comprehensive model to be used in accounting for revenue arising from contracts with customers and supersedes previous revenue recognition guidance. The standard’s core principle is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. In addition, the standard requires disclosure of the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers. The Company adopted this standard effective January 1, 2019.

In August 2016, the FASB issued ASU 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments*, providing guidance on the classification of certain cash receipts and payments in the statement of cash flows intended to reduce diversity in practice, including cash flows related to debt prepayment or extinguishment costs and contingent consideration that may be paid following a business combination. The Company adopted this new guidance on January 1, 2020 without material impact on our condensed consolidated financial position or results of operations.

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework*. The purpose of the update is to improve the effectiveness of the fair value measurement disclosures that allows for clear communication of information that is most important to the users of financial statements. There were certain required disclosures that have been removed or modified. In addition, the update added the following disclosures: (i) changes in unrealized gains and losses for the period included in other comprehensive income (loss) for recurring Level 3 fair value measurements held at the end of the reporting period and (ii) the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements. The Company adopted this new guidance on January 1, 2020 without material impact on our condensed consolidated financial position or results of operations.



In November 2018, the FASB issued ASU 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction Between Topic 808 and Topic 606*, which clarifies that certain transactions between collaborative arrangement participants should be accounted for as revenue under ASC 606 when the collaborative arrangement participant is a customer for a promised good or service that is distinct within the collaborative arrangement. The guidance also precludes entities from presenting amounts related to transactions with a collaborative arrangement participant that is not a customer as revenue, unless those transactions are directly related to third-party sales. The Company adopted this new guidance on January 1, 2020 without material impact on our condensed consolidated financial position or results of operations.

*Recent Accounting Pronouncements Not Adopted as of March 31, 2020:*

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments – Credit Losses (Topic 326)*, amending existing guidance on the accounting for credit losses on financial instruments within its scope. The guidance introduces an expected loss model for estimating credit losses, replacing the incurred loss model. The new guidance also changes the impairment model for available-for-sale debt securities, requiring the use of an allowance to record estimated credit losses (and subsequent recoveries). The new guidance is effective for the Company beginning after December 15, 2020. The Company is currently evaluating the impact of the adoption of this guidance on its condensed consolidated financial statements.

In August 2018, the FASB issued ASU 2018-15, *Intangibles—Goodwill and Other Internal-Use Software (Subtopic 350-40: Customer’s Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That is a Service Contract)*, which aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software. The update provides guidance distinguishing between capitalizable service contract implementation costs and contract costs required to be expense. In addition, the update requires that the term of the hosting arrangement is to include the non-cancelable period of the arrangement plus periods covered by (i) an option to extend the arrangement if the customer is reasonably certain to exercise that option; (ii) an option to terminate the arrangement if the customer is reasonably certain not to exercise the termination option and (iii) an option to extend (or not to terminate) the arrangement in which exercise of the option is in the control of the vendor. This standard will become effective for the Company beginning January 1, 2021. The amendments may be applied either retrospectively or prospectively to all implementation costs incurred after the date of adoption. The Company is currently evaluating the impact of ASU 2018-15 on its consolidated financial statements.

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740), Simplifying the Accounting for Income Taxes*, which amends accounting for income taxes during interim periods and makes changes to certain income tax classifications. The new standard allows exceptions to the use of the incremental approach for intra-period tax allocation, when there is a loss from continuing operations and income or a gain from other items, and to the general methodology for calculating income taxes in an interim period, when a year-to-date loss exceeds the anticipated loss for the year. The standard also requires franchise or similar taxes partially based on income to be reported as income tax and the effects of enacted changes in tax laws or rates to be included in the annual effective tax rate computation from the date of enactment. The standard will be effective for the Company beginning January 1, 2022, with early adoption of the amendments permitted. The Company is currently evaluating the impact from the adoption of ASU 2019-12 on its consolidated financial statements

Other pronouncements issued by the FASB or other authoritative accounting standards groups with future effective dates are either not applicable or not significant to the condensed consolidated financial statements of the Company.

**Note 4. Risks and Uncertainties**

The Company’s cash requirements for 2020 and beyond include expenses related to continuing development and clinical evaluation of its products, costs of regulatory filings, patent prosecution expenses and litigation expenses, expenses related to commercialization of its products, as well as costs to comply with the requirements of being a public company. As of March 31, 2020, working capital (current assets minus current liabilities) totaled \$35,726, which included \$35,521 of cash and cash equivalents.

As of March 31, 2020, Aquestive has experienced a history of net losses and the Company’s accumulated deficits totaled \$147,004, which have been partially funded by profits from manufacture and supply operations, licensing revenues and certain other services, with the balance of the related funding requirements met by the Company’s equity and debt securities offerings and 12.5% Senior Secured Notes due 2025. In 2019, the Company raised funding totaling \$52,226, consisting of net proceeds of \$13,110 from the refinancing of its debt in July, \$37,295 from the public offering of 8,050,000 common shares in December 2019, and \$1,821 from the exercise of warrants issued in connection with the aforementioned debt refinancing.

In addition to the characteristics described above, the nature of which provide indications that the Company's ability to execute its near-term business objectives and achieve profitability over the longer term cannot be assured, management views the impact of COVID-19 on the economy, its industry and its own operations as rapidly evolving, the future effects of which are highly uncertain and currently unpredictable. Due to current or future interruptions and possible disruptions in health services, FDA operations, freight and other transportation services, supply, manufacturing, workforce health, availability of favorable financial markets and other essential human and business requirements, the possibility exists that the severity, rapidity of the spread, and the duration of the COVID-19 pandemic may be expected to negatively affect such areas as pre-clinical and clinical trials of our product candidates, regulatory review and approval of our product candidates, customer demand for our products and services, our customers' ability to pay for goods and services, uninterrupted supply of pharmaceutical ingredients and other raw materials from our approved vendors, ongoing availability of an appropriate labor force and skilled professionals, and additional capital from debt or equity investors.

Subject to and absent any material adverse effect of these and other possible COVID-19 effects, the Company expects that its anticipated revenues from licensed and proprietary products, cash on hand and the funds received from the equity offering, potential monetization of its out-licensed apomorphine product candidate, subject to regulatory approval which cannot be assured, and access to the capital markets under its shelf registration statement, would be adequate to meet expected operating, investing, and financing needs for the next twelve months. To the extent additional funds are necessary to meet liquidity needs as the Company continues to execute its business strategy, the Company anticipates that additional funding requirements will be obtained through monetization of certain royalty streams or through availability of additional debt or equity financings, and continuing expense reduction initiatives, or a combination of these potential sources of funds, although the Company can provide no assurance that these sources of funding will be available on reasonable terms, if at all, and we could be required to utilize available financial resources sooner than expected. We have based this expectation on assumptions that could change or prove to be inaccurate, either due to the impact of COVID-19 or to unrelated factors including factors arising in the capital markets, asset monetization markets, regulatory approval process, regulatory oversight and other factors.

#### **Note 5. Revenues and Trade Receivables, Net**

Our revenues to date have been earned from our product development pipeline, marketed product activities and self-developed medicines. These activities generate revenues in four primary categories: manufacturing and supply revenue, co-development and research fees, license and royalty revenue, and proprietary product sales, net.

#### ***Performance Obligations***

A performance obligation is a promise in a contract to transfer a distinct good or service to the customer and is the unit of account in the current revenue standard. A contract's transaction price is allocated to each distinct performance obligation and recognized as revenue when, or as, the performance obligation is satisfied. At contract inception, we assess the goods promised in our contracts with customers and identify a performance obligation for each promise to transfer to the customer a good that is distinct. When identifying our performance obligations, we consider all goods or services promised in the contract regardless of whether explicitly stated in the customer contract or implied by customary business practices. The Company's performance obligations consist mainly of transferring control of goods and services identified in the contracts, purchase orders or invoices.

The Company's performance obligation with respect to its proprietary product sales is satisfied at a point in time which transfers control upon delivery of the product to its customers. The Company considers control to have transferred upon delivery because the customer has legal title to the asset, physical possession of the asset has been transferred, the customer has significant risks and rewards of ownership of the asset and the Company has a present right to payment at that time. With respect to manufacturing and supply revenue stream, a quantity is ordered and manufactured according to customer's specifications and represents a single performance obligation. The products manufactured are exclusively for specific customers and have no alternative use. Under the customer arrangements, the Company is entitled to receive payments for progress made to date once the acceptance requirements surrounding quality control are satisfied. Thus, revenues related to this product stream are recognized at the point in time when the manufactured product passes quality control.

Royalty revenues are estimated based on the provisions of contracts with customers and recognized in the same period that the royalty-based products are sold to the Company's strategic partners, as all royalties are directly attributable to the Company's manufacturing activities, and are therefore recognizable at the same time the manufacturing revenue is recognizable. In addition to usage-based royalties, licensing contracts may contain provisions for one-time payments related to certain license fees and milestone achievements. Revenue recognition of these license fees and milestone payments depend on the nature of the specific contract; typically license and milestone payments are recognized at a point in time in the period they are achieved. However, there are limited instances where upon review of the contract, it is determined that the license is non-distinct and limited in nature and does not provide benefit to the customer without purchasing the product, these upfront licensing fees are recognized over time (typically the length of the contract).

Co-development and research fee revenue is recorded over time based upon the progress of services provided in order to complete the specific performance obligation identified in the related contract.

Revenues from sale of products and services and the subsequent related payments are evidenced by a contract with the customer, which includes all relevant terms of sale. For manufacturing and supply and proprietary product sales, invoices are generally issued upon the transfer of control and co-development and research revenue is typically invoiced based on the contractual payment schedule, or upon completion of the service. Invoices are typically payable 30 to 60 days after the invoice date, however some payment terms may reach 105 days depending on the customer. The Company performs a review of each specific customer's creditworthiness and ability to pay prior to acceptance as a customer. Further, the Company performs periodic reviews of its customers' creditworthiness prospectively.

### **Contract Assets**

In limited situations, certain customer contractual payment terms require us to bill in arrears; thus, we satisfy some, or all, of our performance obligations before we are contractually entitled to bill the customer. In these situations, billing occurs subsequent to revenue recognition, which results in a contract asset. We reflect these contract assets as a component of other receivables within Trade and other receivables on the Condensed Consolidated Balance Sheet. As of March 31, 2020, and December 31, 2019, such contract assets were \$1,458, and \$4,363, respectively.

### **Contract Liabilities**

In other limited situations, certain customer contractual payment terms allow us to bill in advance; thus, we receive customer cash payment before satisfying some or all of our performance obligations. In these situations, billing occurs in advance of revenue recognition, which results in contract liabilities. We reflect these contract liabilities as deferred revenue on our Consolidated Balance Sheet. As we satisfy our remaining performance obligations, we release a portion of the deferred revenue balance. As of March 31, 2020, and December 31, 2019, such contract liabilities were \$4,872 and \$5,154, respectively.

The Company's revenues were comprised of the following:

	<b>Three Months Ended March 31,</b>	
	<b>2020</b>	<b>2019</b>
Manufacture and supply revenue	\$ 6,916	\$ 6,669
License and royalty revenue	426	4,622
Co-development and research fees	263	770
Proprietary product sales, net	1,160	582
<b>Total revenues</b>	<b>\$ 8,765</b>	<b>\$ 12,643</b>

### **Disaggregation of Revenue**

The following table provides disaggregated net revenue by geographic area:

	<b>Three Months Ended March 31,</b>	
	<b>2020</b>	<b>2019</b>
United States	\$ 7,506	\$ 12,394
Ex-United States	1,259	249
<b>Total revenues</b>	<b>\$ 8,765</b>	<b>\$ 12,643</b>

Non-United States revenues is derived primarily from products manufactured for the Australian and Malaysian markets.

Trade and other receivables, net consist of the following:

	<u>March 31,</u> <u>2020</u>	<u>December 31,</u> <u>2019</u>
Trade receivables	\$ 8,470	\$ 9,094
Contract and other receivables	1,406	4,363
Less: allowance for bad debt	(84)	(124)
Less: sales-related allowances	(256)	(203)
Trade and other receivables, net	<u>\$ 9,536</u>	<u>\$ 13,130</u>

Other receivables totaled \$1,406 and \$4,363 as of March 31, 2020 and December 31, 2019, respectively, consisting primarily of reimbursable costs incurred on behalf of customers for which earnings processes have been met prior to shipment of goods or full delivery of completed services. Sales-related allowances for both periods presented are estimated in relation to revenues recognized for sales of Sympazan®.

The following table presents the changes in the allowance for bad debt:

	<u>March 31,</u> <u>2020</u>	<u>December 31,</u> <u>2019</u>
Allowance for doubtful accounts at beginning of period	\$ 124	\$ 58
(Reversals)/additions charged to bad debt expense	(40)	66
Recoveries from amounts previously reserved	--	—
Allowance for doubtful accounts at end of period	<u>\$ 84</u>	<u>\$ 124</u>

### ***Sales Related Allowances and Accruals***

Revenues from sales of products are recorded net of prompt payment discounts, wholesaler service fees, returns allowances, rebates and co-pay support programs. These reserves are based on estimates of the amounts earned or to be claimed on the related sales. These amounts are treated as variable consideration, estimated and recognized as a reduction of the transaction price at the time of the sale. The Company includes these estimated amounts in the transaction price to the extent it is probable that a significant reversal of cumulative revenue recognized for such transaction will not occur, or when the uncertainty associated with the variable consideration is resolved. The calculation of some of these items requires management to make estimates based on sales data, historical return data, contracts and other related information that may become known in the future. The adequacy of these provisions is reviewed on a quarterly basis.

The following table provides a summary of activity with respect to our sales related allowances and accruals for the three months ended March 31, 2020:

	<u>Total Sales Related</u> <u>Allowances and Accruals</u>
<b>Balance at December 31, 2019</b>	<u>\$ 1,377</u>
Provision related to sales during the period	1,157
Credits and payments	(867)
<b>Balance at March 31, 2020</b>	<u>\$ 1,667</u>

Total reductions of gross product sales from sale-related allowances and accruals were \$1,157 for the three months ended March 31, 2020. Accruals for returns allowances and prompt pay discounts are reflected as a direct reduction to trade receivable and accruals for wholesaler fees, co-pay cards and rebates as current liabilities. The accrued balances relative to these provisions included in Trade and other receivables, net and Accounts payable and accrued expenses were \$256 and \$1,411, respectively, at March 31, 2020 and \$203 and \$1,174, respectively, at December 31, 2019.

### ***Concentration of Major Customers***

Customers are considered major customers when sales exceed 10% of total net sales for the period or outstanding receivable balances exceed 10% of total receivables. For the year ended at December 31, 2019, Indivior, Inc. (“Indivior”) provided 86% of the total revenues for the period, and as of that date, the Company’s outstanding receivable balance from Indivior represented approximately 80% of gross receivables. For the three months ended March 31, 2020, revenues provided by Indivior represented approximately 79% of total revenue, and outstanding accounts receivable due from Indivior represented approximately 63% of gross receivables.

## **Note 6. Material Agreements**

### ***Commercial Exploitation Agreement with Indivior***

In August 2008, the Company entered into a Commercial Exploitation Agreement with Reckitt Benckiser Pharmaceuticals, Inc. (with subsequent amendment collectively, the “Indivior License Agreement”). Reckitt Benckiser Pharmaceuticals, Inc. was later succeeded to in interest by Indivior, Inc. Pursuant to the Indivior License Agreement, the Company agreed to manufacture and supply Indivior’s requirements for Suboxone, a sublingual film formulation, both inside and outside the United States on an exclusive basis.

Under the terms of the Indivior License Agreement, the Company is required to manufacture Suboxone in accordance with current Good Manufacturing Practice standards and according to the specifications and processes set forth in the related quality agreements the Company entered into with Indivior. Additionally, the Company is required to obtain Active Pharmaceutical Ingredients (“API”) for the manufacture of Suboxone directly from Indivior. The Indivior License Agreement specifies a minimum annual threshold quantity of Suboxone that the Company is obligated to fill and requires Indivior to provide the Company with a forecast of its requirements at various specified times throughout the year.

The Indivior License Agreement provides for payment by Indivior of a purchase price per unit that is subject to adjustment based on our ability to satisfy minimum product thresholds. Additionally, in the event Indivior purchases certain large quantities of Suboxone during a specified period, Indivior will be entitled to scaled rebates on its purchases.

In addition to the purchase price for the Suboxone supplied, Indivior is required to make certain single digit percentage royalty payments tied to net sales value (as provided for in the Indivior License Agreement) in each of the United States and in the rest of the world subject to annual maximum amounts and limited to the life of the related United States or international patents. In 2012, Indivior exercised its right to buy out its future royalty obligations in the United States under the Indivior License Agreement. Indivior remains obligated to pay royalties for all sales outside the United States.

The Indivior License Agreement contains customary contractual termination provisions, including, with respect to a filing for bankruptcy or corporate dissolution, an invalidation of the intellectual property surrounding Suboxone, or commission of a material breach of the Indivior License Agreement by either party. Additionally, Indivior may terminate the Indivior License Agreement if the U.S. Food and Drug Administration (“FDA”) or other applicable regulatory authority declares the Company’s manufacturing site to no longer be suitable for the manufacture of Suboxone or Suboxone is no longer suitable to be manufactured due to health or safety reasons. The initial term of the Indivior License Agreement was seven years from the commencement date. Thereafter, the Indivior License Agreement automatically renews for successive one-year periods, unless either party provides the other with written notice of its intent not to renew at least one year prior to the expiration of the initial or renewal term.

### ***Supplemental Agreement with Indivior***

On September 24, 2017, the Company entered into an agreement with Indivior, or the Indivior Supplemental Agreement. Pursuant to the Indivior Supplemental Agreement, the Company conveyed to Indivior all existing and future rights in the settlement of various ongoing patent enforcement legal actions and disputes related to the Suboxone product. The Company also conveyed to Indivior the right to sublicense manufacturing and marketing capabilities to enable an Indivior licensed generic buprenorphine product to be produced and sold by parties unrelated to Indivior or Aquestive. Under the Indivior Supplemental Agreement, the Company is entitled to receive certain payments from Indivior commencing on the date of the agreement through January 1, 2023. Once paid, all payments made under the Indivior Supplemental Agreement are non-refundable. Through February 20, 2019, the at-risk launch date of the competing generic products of Dr. Reddy’s Labs and Alvogen, the Company received an aggregate of \$40,750 from Indivior under the Indivior Supplemental Agreement, of which \$4,250 was collected during the three months ended March 31, 2019. Further payments under the Indivior Supplemental Agreement were suspended until adjudication of related patent infringement litigation is finalized. If such litigation is successful, in addition to the amounts already received as described in the foregoing, the Company may receive up to an additional \$34,250, consisting of (i) up to \$33,000 in the aggregate from any combination of (a) performance or event-based milestone payments and (b) single digit percentage royalties on net revenue earned by Indivior on sales of Suboxone and (ii) an additional \$1,250 that was earned through the issuance of additional process patent rights to the Company. The aggregate payments under this Indivior Supplemental Agreement are capped at \$75,000.

All payments made by Indivior to the Company pursuant to the Indivior Supplemental Agreement are in addition to, and not in place of, any amounts owed by Indivior to the Company pursuant to the Indivior License Agreement. Indivior’s payment obligations under the Indivior Supplemental Agreement are subject to certain factors affecting the market for Suboxone and may terminate prior to January 1, 2023 in the event certain contingencies relating to such market occur.



### **License Agreement with Sunovion Pharmaceuticals, Inc.**

In April 2016, we entered into a license agreement with Cynapsus Therapeutics Inc. (which was later succeeded to in interest by Sunovion Pharmaceuticals, Inc., or “Sunovion”) referred to as the Sunovion License Agreement, pursuant to which we granted Sunovion an exclusive, worldwide license (with the right to sub-license) to certain intellectual property, including existing and future patents and patent applications, covering all oral films containing APL-130277 (apomorphine) for the treatment of off episodes in Parkinson’s disease patients, as well as two other fields. Our licensee, Sunovion, as sponsor of APL-130277, submitted a New Drug Application (“NDA”) to the FDA on March 29, 2018. According to public statements by Sunovion, following the January 2019 PDUFA date, Sunovion received a Complete Response Letter from the FDA which requires additional data, but does not require additional clinical studies. In the 2019 fourth quarter, Sunovion announced that it had received from the FDA a Prescription Drug User Fee Act (PDUFA) date of May 21, 2020 after the submission of its NDA.

In consideration for the rights granted to Sunovion under the Sunovion License Agreement, the Company received aggregate payments totaling \$18,000 to date. In addition to the upfront payment of \$5,000, the Company also earned an aggregate of \$13,000 in connection with specified regulatory and development milestones in the United States and Europe (the “Initial Milestone Payments”), all of which of which has been received to date. No payments were received during the three-month period ended March 31, 2020 and 2019, respectively. The Company is also entitled to receive certain contingent one-time milestone payments related to product availability and regulatory approval in the United States and Europe, certain one-time milestone payments based on the achievement of specific annual net sales thresholds of APL-130277, and ongoing mid-single digit percentage royalty payments related to the net sales of APL-130277, (subject to reduction to low-single digit percentage royalty payments in certain circumstances), subject to certain minimum payments. The maximum aggregate milestone payments that may be paid to the Company pursuant to the Sunovion License Agreement is equal to \$45,000. With the exception of the Initial Milestone Payments, there can be no guarantee that any such milestones will in fact be met or that additional milestone payments will be payable.

Effective March 16, 2020, the Company entered into a first amendment (the “Amendment”) to the License Agreement (the “Agreement”) dated as of April 1, 2016. The Amendment was entered into for the primary purpose of amending the Agreement as follows: (i) including the United Kingdom and any other country currently in the European Union (EU) which later withdraws as a member country in the EU for purpose of determining the satisfaction of the condition triggering the obligation to pay the third milestone due under the Agreement, (ii) extending the date after which Sunovion has the right to terminate the Agreement for convenience from December 31, 2024 to May 31, 2028, (iii) modifying the date the first minimum annual royalty is due to be paid by Sunovion to the Company from January 1, 2020 to April 1, 2020 and (iv) modifying the termination provisions to reflect the Company’s waiver of the right to terminate the Agreement in the event that the licensed product was not commercialized by January 1, 2020. This Sunovion License Agreement will continue until terminated by Sunovion in accordance with the termination provisions of the Amendment to the Sunovion License Agreement. The Sunovion License Agreement continues (on a country-by-country basis) until the expiration of all applicable licensed patents. Upon termination of the Sunovion License Agreement all rights to intellectual property granted to Sunovion to develop and commercialize products will revert to the Company and Sunovion must continue to pay royalties to the Company on each sale of Sunovion's remaining inventory of products commercialized by Sunovion which include apomorphine as their API.

### **Agreement to Terminate CLA with KemPharm**

In March 2012, the Company entered into an agreement with KemPharm, Inc. (“KemPharm”) to terminate a Collaboration and License Agreement entered into by the Company and KemPharm during April 2011. Under this termination arrangement, the Company has the right to participate in any and all value that KemPharm may derive from the commercialization or any other monetization of KemPharm’s KP-415 and KP-484 compounds or their derivatives. Among these monetization transactions are those related to any business combinations involving KemPharm and collaborations, royalty arrangements, or other transactions from which KemPharm may realize value from these compounds. During September 2019, the Company received \$1,000 from its 10% share of milestone payments paid to KemPharm under its licensing of KP-415 and KP-484 to a third party. There can be no guarantee that any such payments will be made in the future. The Company has not received payments under this arrangement during the three-month periods ended at March 31, 2020 and 2019, respectively.

## Note 7. Financial Instruments – Fair Value Measurements

Certain assets and liabilities are reported on a recurring basis at fair value. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1 – Quoted prices in active markets for identical assets or liabilities. Cash and cash equivalents consisted of cash in bank checking accounts and money market funds which are all Level 1 assets.
- Level 2 – Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data. The Company currently has no Level 2 assets or liabilities.
- Level 3 – Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques. As of March 31, 2020 and 2019, respectively, the Company has no Level 3 assets or liabilities.

The carrying amounts reported in the balance sheets for trade and other receivables, prepaid and other current assets, accounts payable and accrued expenses, and deferred revenue approximate fair value based on the short-term maturity of these assets and liabilities.

The Company granted warrants to certain holders of its Notes in connection with its debt refinancing during 2019. These warrants were valued based on Level 3 inputs and their fair value was based primarily on an independent third-party appraisal prepared as of the grant date consistent with generally-accepted valuation methods of the Uniform Standards of Professional Appraisal Practice, the American Society of Appraisers and the American Institute of Certified Public Accountants' Accounting and Valuation Guide, Valuation of Privately-Held Company Equity Securities Issued Compensation. See Note 14 for further information on these warrants.

## Note 8. Inventories, Net

The components of Inventory, net is as follows:

	<u>March 31,</u> <u>2020</u>	<u>December 31,</u> <u>2019</u>
Raw material	\$ 1,285	\$ 1,244
Packaging material	1,101	1,096
Finished goods	701	519
Total inventories, net	<u>\$ 3,087</u>	<u>\$ 2,859</u>

## Note 9. Property and Equipment, Net

	<u>Useful Lives</u>	<u>March 31,</u> <u>2020</u>	<u>December 31,</u> <u>2019</u>
Machinery	3-15 yrs	\$ 21,088	\$ 21,088
Furniture and fixtures	3-15 yrs	1,203	1,150
Leasehold improvements	(a)	21,333	21,333
Computer, network equipment and software	3-7 yrs	2,790	2,787
Construction in progress		1,403	1,412
		<u>47,817</u>	<u>47,770</u>
Less: accumulated depreciation and amortization		<u>(38,758)</u>	<u>(38,044)</u>
Total property and equipment, net		<u>\$ 9,059</u>	<u>\$ 9,726</u>

(a) Leasehold improvements are amortized over the shorter of the lease term or their estimated useful lives.

Total depreciation and amortization related to property and equipment was \$714 and \$736 for the three-month periods ended at March 31, 2020 and 2019, respectively.

## Note 10. Right-of-Use Assets and Lease Obligations

The Company leases all realty used as its production and warehouse facilities, corporate headquarters, commercialization operations center and research and laboratory facilities. None of these three leases include the characteristics specified in ASC 842, *Leases*, that require classification as financing leases and accordingly, these leases are accounted for as operating leases. These leases provide remaining terms between 3.0 years and 6.5 years, including renewal options expected to be exercised to extend the lease periods. Measurement of the operating lease liability reflects an estimated discount rate of 16.9% applied to minimum lease payments, including expected renewals, based on the incremental borrowing rate experienced in the Company's latest collateralized debt refinancing. For the three months ended March 31, 2020, total operating lease expenses under these leases was \$442, including variable lease expenses such as common area maintenance and operating costs totaling \$106.

Maturities of the Company's operating lease liabilities are as follows:

Remainder of 2020	\$	910
2021		1,287
2022		1,295
2023		944
2024		565
2025		565
2026		424
Total lease payments		<u>5,990</u>
Less: imputed interest		<u>(1,957)</u>
Total operating lease liabilities	\$	<u><u>4,033</u></u>

## Note 11. Intangible Assets, Net and Other Assets

The following table provides the components of identifiable intangible assets, all of which are finite lived, and other assets:

	<u>March 31,</u> <u>2020</u>	<u>December 31,</u> <u>2019</u>
Purchased technology-based intangible	\$ 2,358	\$ 2,358
Purchased patent	509	509
	<u>2,867</u>	<u>2,867</u>
Less: accumulated amortization	(2,727)	(2,714)
Intangible assets, net	<u>140</u>	<u>153</u>
Other assets, primarily security deposits	288	286
Total Intangible assets, net and other assets	<u>\$ 428</u>	<u>\$ 439</u>

Amortization expense was \$13 for each of the three-month periods ended March 31, 2020 and 2019, respectively. During the remaining life of the purchased patent, estimated annual amortization expense is \$50 for each of the years from 2020 to 2022.

## Note 12. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consisted of the following:

	<u>March 31,</u> <u>2020</u>	<u>December 31,</u> <u>2019</u>
Accounts payable	\$ 10,283	\$ 12,274
Accrued compensation	1,929	3,758
Real estate and personal property taxes	370	300
Accrued distribution expenses	1,411	1,174
Other	97	243
Total accounts payable and accrued expenses	<u>\$ 14,090</u>	<u>\$ 17,749</u>



**Note 13. 12.5% Senior Secured Notes and Loans Payable****12.5% Senior Secured Notes**

On July 15, 2019, the Company completed a private placement of up to \$100 million aggregate principal of its 12.5% Senior Secured Notes due 2025 (the “Notes”) and issued warrants for two million shares of common stock (the “Warrants”), \$.001 par value per share, through the structuring agent, Morgan Stanley & Co., LLC, and entered into a purchase agreement and related agreements including a Collateral Agreement with U.S. Bank National Association, as trustee and collateral agent, and a Lien Subordination and Intercreditor Agreement for the benefit of Madryn Health Partners, other institutional noteholders and U.S. Bank National Association in dual roles providing terms and governing an asset-based loan facility.

Upon closing of the Indenture for such Notes (“Indenture”), the Company issued \$70,000 of the principal of the Notes (the “Initial Notes”) along with the Warrants and rights of first offer (the “First Offer Rights”) to the lenders participating in this transaction for Notes and Warrants (the “Lenders”). Issuance of the Initial Notes and Warrants provided net proceeds of \$66,082. In addition to the Initial Notes, the Indenture may provide access to further loans of up to \$30,000 that may become available in two tranches of Additional Notes tied to the NDA filing for and FDA U.S. marketing approval of Libervant™, an important part of our drug candidate pipeline. Provided that no events of default exist, the Company may elect to, and subject to approval of the holder of a majority of the outstanding principal amount of the Notes, in its discretion, to offer to the Lenders participation in a \$10,000 additional offering of 12.5% senior secured notes (the “First Additional Offering”) under terms similar to the Initial Notes, on or before March 31, 2021, upon the filing of the Libervant NDA with the FDA. A second identical funding opportunity would allow the Company to obtain, on or before March 31, 2021, an additional \$20,000 if the first option has been elected and funded, or, if not elected or funded, an additional \$30,000 may be offered for issuance following FDA approval of Libervant for marketing in the U.S. There can be no assurance that any additional financing will be consummated.

Proceeds from issuance of the Initial Notes and Warrants were used to fully repay the Company’s \$56,340 outstanding indebtedness to Perceptive Credit Opportunities Fund, LP (the “Perceptive Loan”), related early repayment fees and legal and other fees incurred to obtain the loan.

The Notes provide a stated fixed rate of 12.5%, payable quarterly in arrears, with the initial quarterly principal repayment of the Initial Notes due on September 30, 2021, and the final quarterly payment due at maturity on June 30, 2025. Principal payments are scheduled to increase annually from 10% of the face amount of debt then outstanding during the first four quarters to 40% of the initial loan principal during the final four quarters.

A debt maturity table is presented below:

Remainder of 2020	\$	-
2021		3,500
2022		10,500
2023		17,500
2024		24,500
2025		14,000
<b>Total</b>	<b>\$</b>	<b><u>70,000</u></b>

The Company may elect, at its option, to prepay the Notes at any time at premiums that range from 101.56% of outstanding principal if prepayment occurs on or after the 5<sup>th</sup> anniversary of the issue date of the Notes to 112.5% if payment occurs during the third year after the issuance of the Notes. In the event that redemption occurs within the two years after the issuance of the Notes, a make-whole fee is required, based on the present value of remaining interest payments using an agreed-upon discount rate linked to the then-current U.S. Treasury rate. The Indenture also includes a change of control provision under which the Company may be required to repurchase the Notes at 101% of the remaining principal plus accrued interest at the election of the Lenders.

Collateral for the loan under the Notes consists of a priority lien on substantially all property and assets, including intellectual property, of the Company. This secured obligation provides payment rights that are senior to all existing and future subordinated indebtedness of the Company and provides Lenders with perfected security interests in substantially all of the Company's assets. In the event that asset-based loans of up to \$10,000 ("ABL Facility") may be obtained, subject receivables and inventory assets will provide a second priority lien to senior secured Noteholders. The Company's license of its IP to a third-party drug development enterprise (specifically, Sunovion's APL-130277 product) is one of the various assets serving as collateral for the loan. The Indenture permits the Company to monetize this asset while specifying that a portion of the proceeds, up to \$40,000 if the First Additional Offering has not been elected or funded, or, \$50,000 if it has been elected and funded, must be applied to prepay the Initial Notes, at 112.5% of the principal amount of the Notes being repurchased, plus accrued and unpaid interest, if any, thereon, to the date of the repurchase, to the extent elected by the Note holders, assuming that such monetization, up to such \$40,000 or \$50,000 level, as applicable, equals or exceeds those levels and if such monetization does not equal or exceed such level, such prepayment would pro-rated among the Note holders. To the extent that Lenders do not elect repayment of the debt at the date of the monetization, the amount not elected up to \$40,000 (or \$50,000 if an additional tranche is issued) will be held in a collateral account until approval of Libervant by the FDA for U.S. marketing, at which time this cash collateral is to be released to the Company. Proceeds in excess of \$40,000 (or \$50,000 if an additional tranche is issued) can be used immediately for general corporate purposes. As of March 31, 2020, the Company was in compliance with all of its covenants.

The Company capitalizes legal and other third-party costs incurred in connection with obtaining debt as deferred debt issuance costs and applies the unamortized portion as a reduction of the outstanding face amount of the related loan in accordance with ASU 2015-03, *Interest – Imputation of Interest: Simplifying the Presentation of Debt Issuance Costs*. Similarly, the Company amortizes debt discounts, such as those represented by warrants issued to its leaders, and offsets those as a direct reduction of its outstanding debt. Amortization expenses arising from deferred debt issuance costs and debt discounts related to the Notes were \$584 for the three months ended March 31, 2020, while comparative amortization expenses derived from deferred debt issuance costs and debt discounts related to the Perceptive Loan for the three months ended March 31, 2019 were \$389. Unamortized deferred debt issuance costs and deferred debt discounts total \$9,078 and \$9,662 as of March 31, 2020 and December 31, 2019, respectively.

#### *Loans Payable - Perceptive*

In August 2016, the Company entered into a Loan Agreement and Guaranty with Perceptive Credit Opportunities Fund, LP ("Perceptive") under which the total available facility of \$50,000 had been borrowed as of March 2017. At closing, Perceptive received a warrant to purchase senior common equity interests representing 4.5% of the fully diluted common units of the Company on an as converted basis, which was automatically exercised in full at the time of Aquestive's IPO. In May 2018, the Company and Perceptive agreed to make certain amendments to the loan agreement then in effect that provided for: (1) the postponement of the initial loan principal payment to May 2019, (2) a delay of the loan maturity date to December 16, 2020 and (3) with Perceptive's consent, an agreement to permit monetization of the royalties and fees that may be derived from sales of certain apomorphine products and a concurrent agreement for the release of the liens related to these royalties and fees.

In July 2019, the Perceptive Loan was paid in full in connection with the completion of the sale of the 12.5% Notes and Warrants described above. The early extinguishment of this debt resulted in a charge to third quarter 2019 earnings of an amount of \$4,896, including an early retirement premium of \$2,944 and the remaining balances of the unamortized loan discount and loan acquisition costs.

#### **Note 14. Warrants Issued to 12.5% Senior Secured Noteholders**

The Warrants that were issued in conjunction with the 12.5% Senior Secured Notes (the "Notes") expire on June 30, 2025 and entitle the holders of the Notes to purchase two million shares of the Company's common stock at \$4.25 per share and include specified registration rights. Management estimated the fair value of the Warrants to be \$6,800, assisted by an independent third-party appraiser. The fair value of these Warrants is treated as a debt discount, amortizable over the term of the Warrants, with the unamortized loan portion applied to reduce the face amount of the Notes in the Company's balance sheet. Additionally, since the Warrants issued do not provide warrant redemption or put rights within the control of the holders that could require the Company to make a payment of cash or other assets to satisfy the obligations under the Warrants, except in the case of a "cash change in control", the fair value attributed to the Warrants is presented in additional-paid in capital in the accompanying Condensed Consolidated Balance Sheets.

Certain holders of the Notes exercised Warrants for the purchase of 428,571 shares of common stock, and proceeds totaling \$1,821 were received on December 16, 2019. There were no Warrants exercised by the holders of the Notes during the three-month period ended at March 31, 2020.

#### **Note 15. Net Loss Per Share**

Basic net loss per share is calculated by dividing net loss by the weighted-average number of common shares.

As a result of the Company's net losses incurred for the three-month periods ended at March 31, 2020 and 2019, respectively, all potentially dilutive instruments outstanding would have anti-dilutive effects on per-share calculations for this period. Therefore, basic and diluted net loss per share were the same, as reflected below.

	<b>Three Months Ended at March 31,</b>	
	<b>2020</b>	<b>2019</b>
Numerator:		
Net loss	\$ (16,530)	\$ (14,726)
Denominator:		
Weighted-average number of common shares – basic and diluted	33,569,694	24,963,603
Net loss per common share – basic and diluted	\$ (0.49)	\$ (0.59)

As of March 31, 2020 and 2019, respectively, the Company's potentially dilutive instruments included 2,947,192, and 1,732,426 options to purchase common shares and 44,036 and 172,655 unvested RSUs that were excluded from the computation of diluted weighted average shares outstanding because these securities had an anti-dilutive impact due to the losses reported. Similarly excluded as of March 31, 2020 were potentially dilutive warrants for the purchase of 1,571,429 common shares. No such dilutive warrants were issued as of March 31, 2019.

### Note 16. Share-Based Compensation

The Company recognized share-based compensation in its Condensed Consolidated Statements of Operations and Comprehensive Loss during 2020 and 2019, respectively, as follows:

	<b>Three Months Ended March 31,</b>	
	<b>2020</b>	<b>2019</b>
Expense classification:		
Manufacture and supply	\$ 63	\$ 44
Research and development	182	208
Selling, general and administrative	1,615	1,268
Total share-based compensation expenses	\$ 1,860	\$ 1,520
Share-based compensation from:		
Restricted stock units	\$ 464	\$ 463
Stock options	1,396	1,057
Employee stock purchase plan	—	—
Total share-based compensation expenses	\$ 1,860	\$ 1,520

### Share-Based Compensation Equity Awards

The following tables provide information about the Company's restricted stock units and stock option unit activity during the three months ended March 31, 2020:

#### Restricted Stock Unit Awards (RSUs)

	<b>Number of Units</b>	<b>Weighted Average Grant Date Fair Value Per Share</b>
	(In thousands)	
Unvested at December 31, 2019	74	\$ 14.64
Granted	—	—
Vested	(30)	15.03
Forfeited	—	—
Unvested at March 31, 2020	44	\$ 14.38
Grant date fair value of shares vested during the period	\$ 448	
Unrecognized compensation costs at March 31, 2020	\$ 435	

Unrecognized compensation costs related to awards of RSUs are expected to be recognized over a weighted-average period of less than two years.

Stock option awards

	<b>Number of Options</b>	<b>Weighted Average Exercise Price</b>
	(In thousands)	
Outstanding at December 31, 2019	2,231	\$ 10.42
Granted	716	\$ 1.60
Exercised, Forfeited, Expired	—	
Outstanding at March 31, 2020	2,947	\$ 8.27
Vested or expected to vest at March 31, 2020	2,739	\$ 8.28
Exercisable at March 31, 2020	666	\$ 12.75

The weighted average grant date fair value of stock options granted during 2020 was \$1.26. The fair value of stock options granted were estimated using the Black-Scholes-Merton pricing model based upon the following assumptions:

	<b>Three Months Ended March 31, 2020</b>
Expected dividend yield	None
Expected volatility	100%
Expected term (years)	6.1
Risk-free interest rate	0.6% - 1.7%

During the three months ended March 31, 2020, options were granted with exercise prices ranging from \$1.54 to \$4.17, and accordingly, given Aquestive's share price of \$2.19 at the close of the Company's first quarter of 2020, certain shares granted in 2020 provided intrinsic value of \$456 at March 31, 2020.

As of March 31, 2020, \$8,693 of total unrecognized compensation expenses related to non-vested stock options is expected to be recognized over a weighted average period of 2.1 years from the date of grant.

Employee stock purchase plan

The Company's Board of Directors adopted the Aquestive Therapeutics, Inc. Employee Stock Purchase Plan ("ESPP") in June 2018, as amended and restated effective as of January 1, 2019. Rollout of the ESPP began in late 2018, and initial employee purchases are expected to be made in 2019. The Company may offer common stock purchase rights biannually under offerings that allow for the purchase of common stock at the lower of 85% of the fair value of shares on either the first or last day of the offering period. No purchases under the ESPP occurred in the three months ended March 31, 2020 and 2019, respectively.

**Note 17. Income Taxes**

The Company has accounted for income taxes under the asset and liability method, which requires deferred tax assets and liabilities to be recognized for the estimated future tax consequences attributable to differences between financial statement carrying amounts and respective tax bases of existing assets and liabilities, as well as net operating loss carryforwards and research and development credits. Valuation allowances are provided if it is more likely than not that some portion or all of the deferred tax asset will not be realized. The Company has considered the impact of the CARES Act in relation to the 2020 income tax provision, however due to the full valuation allowance and no ability or intent to carryback the 2020 net operating loss, there is no impact.

The Company's tax provision for interim periods is determined using an estimate of its annual effective tax rate, adjusted for discrete items. For the three months ended March 31, 2020 and 2019, the Company recorded no income tax benefit from its pretax losses of \$16,530 and \$14,726, respectively, due to realization uncertainties.

The Company's U.S. Federal statutory rate is 21%. The primary factor impacting the effective tax rate for the three months ended March 31, 2020 is the anticipated full year operating loss which will require full valuation allowances against any associated net deferred tax assets.

## Note 18. Contingencies

### (A) Litigation and Contingencies

From time to time, the Company has been and may again become involved in legal proceedings arising in the ordinary course of business, including product liability, intellectual property, commercial litigation or environmental or other regulatory matters. Except as described below, Aquestive is not presently a party to any litigation or legal proceedings that is believed to be material.

#### Patent-Related Litigation

Beginning in August 2013, we were informed of abbreviated new drug application (“ANDA”) filings in the United States by Watson Laboratories, Inc. (now Actavis Laboratories, Inc., or “Actavis”), Par Pharmaceutical, Inc. (“Par”), Alvogen Pine Brook, Inc. (“Alvogen”), Teva Pharmaceuticals USA, Inc. (“Teva”), Sandoz Inc. (“Sandoz”), and Mylan Technologies Inc. (“Mylan”), for the approval by the FDA of generic versions of Suboxone Sublingual Film in the United States. We filed patent infringement lawsuits against all six generic companies in the United States District Court for the District of Delaware (the “Delaware District Court”). After the commencement of the ANDA patent litigation against Teva, Dr. Reddy’s Laboratories (“DRL”) acquired the ANDA filings for Teva’s buprenorphine and naloxone sublingual film that are at issue in these trials.

Of these, cases against three of the six generic companies have been resolved.

- *Mylan* and *Sandoz* settled without a trial. *Sandoz* withdrew all challenges and became the distributor of the authorized generic products.
- All cases against *Par* were resolved pursuant to a May 2018 settlement agreement between the Company, Indivior, and *Par* and certain of its affiliates.
- *Actavis* was found to infringe Patent No. 8,603,514, or the ’514 patent, and cannot enter the market until the expiration of the patent in 2024, and the United States Court of Appeals for the Third Circuit (“Federal Circuit”) affirmed that ruling on July 12, 2019.
- *DRL* and *Alvogen* were found not to infringe under a different claim construction analysis, and the Federal Circuit affirmed that ruling on July 12, 2019. *Teva* has agreed to be bound by all DRL adjudications.

Subsequent to the above, all potential generic competitors without a settlement agreement were also sued for infringement of two additional new patents that contain new claims not adjudicated in the original Delaware District Court case against DRL and Alvogen. On July 12, 2019, the Federal Circuit affirmed the decisions from the previously decided cases. The remaining case against Actavis was dismissed in light of the infringement ruling above, which prevents Actavis from entering the market until 2024. The case(s) against the remaining defendants regarding the additional asserted patents have not been finally resolved. A *Markman* hearing in the cases against Dr. Reddy’s and Alvogen which is pending in the United States District Court for the District of New Jersey (the “New Jersey District Court”) was held on October 17, 2019. On November 5, 2019, District Judge McNulty of the New Jersey District Court issued a *Markman* opinion construing the disputed terms of the asserted patents. On January 9, 2020, the New Jersey District Court entered a stipulated order of non-infringement of one of the patents, Patent No. 9,931,305, or the ’305 patent, based on the Federal Circuit’s claim construction ruling, and we and Indivior preserved our rights to appeal the claim construction ruling. On November 19, 2019, Magistrate Judge Waldor of the New Jersey District Court issued an order granting DRL and Alvogen’s requests to file amended answers to add antitrust counterclaims against us and Indivior. We and Indivior appealed the Magistrate Judge’s decision to District Judge McNulty on December 4, 2019, and DRL and Alvogen opposed the appeal. The parties are awaiting further action from the New Jersey District Court on the appeal. On January 17, 2020, we filed a motion to dismiss DRL’s and Alvogen’s antitrust counterclaims for failure to state a claim, and DRL and Alvogen opposed the motion. The parties are awaiting further action from the New Jersey District Court on the motion to dismiss. No trial date has been set in those cases. We are not able to determine or predict the ultimate outcome of this proceeding or provide a reasonable estimate, or range of estimates, of the possible outcomes or loss, if any, in this matter.

On February 19, 2019, the Federal Circuit issued its mandate reversing the New Jersey District Court’s preliminary injunction against Dr. Reddy’s. Following issuance of the mandate, the New Jersey District Court vacated preliminary injunctions against both Dr. Reddy’s and Alvogen. Dr. Reddy’s, Alvogen, and Mylan all launched generic versions of Suboxone Sublingual Film, and the launches by Dr. Reddy’s and Alvogen are “at risk” because the products are the subject of the ongoing patent infringement litigations.

On March 22, 2019, we and Indivior brought suit against Aveva Drug Delivery Systems, Inc., Apotex Corp., and Apotex Inc. in the United States District Court for the Southern District of Florida (the “Southern District of Florida Court”) for infringement of the Company’s U. S. Patent Nos. 8,017,150, 9,687,454, the ’514 patent and ’305 patent, seeking an injunction and potential monetary damages. Following a negotiated settlement between all parties, on December 3, 2019, the parties submitted a Notice of Settlement and a Joint Motion to Approve Consent Judgment. The Southern District of Florida Court entered an order dismissing the suit on December 18, 2019.

We are also seeking to enforce our patent rights in multiple cases against BioDelivery Sciences International, Inc. (“BDSI”). Three cases are currently pending but stayed in the U.S. District Court for the Eastern District of North Carolina (the “Eastern District of North Carolina Court”):

- The first, a declaratory judgment action brought by BDSI against Indivior and Aquestive, seeks declarations of invalidity and non-infringement of U.S. Patents Nos. 7,897,080, 8,652,378 and 8,475,832. This case is stayed pending final resolution of the above-mentioned appeals on related patents.
- The second was filed by us and Indivior related to BDSI’s infringing Bunavail product, and alleges infringement of our patent, U.S. Patent No. 8,765,167, or the ’167 patent, and seeks an injunction and potential monetary damages. Shortly after the case was filed, BDSI filed four (4) IPR’s challenging the asserted ’167 patent. On March 24, 2016, the United States Patent Trial and Appeal Board (“PTAB”), issued a final written decision finding that all claims of the ’167 patent were valid. The case was stayed in May 2016 pending the final determination of the appeals on those decisions. Following the PTAB’s February 7, 2019 decisions on remand denying institution, we and Indivior submitted a notice to the Court on February 15, 2019 notifying the Court that the stay should be lifted as a result of the PTAB’s decisions. We are awaiting further action from the Court.
- On January 13, 2017, we also sued BDSI asserting infringement of the ’167 patent by BDSI’s Belbuca product and seeking an injunction and potential monetary damages. On August 7, 2019, the Eastern District of North Carolina Court granted BDSI’s motion to dismiss the Complaint without prejudice and denied BDSI’s motion to stay as moot. On November 11, 2019, we filed a new Complaint against BDSI in the Eastern District of North Carolina Court. On November 27, 2019, BDSI filed a motion to stay the case pending BDSI’s appeal of the PTAB’s remand decisions, and we opposed the motion. The Eastern District of North Carolina Court denied BDSI’s motion to stay on April 1, 2020. BDSI’s appeal of the PTAB’s remand decisions to the United States Court of Appeals for the Fourth Circuit (the “Federal Fourth Circuit Court”) was docketed on March 13, 2019, and on March 20, 2019, we moved to dismiss the appeal for lack of jurisdiction. On August 29, 2019, the Federal Fourth Circuit Court granted the motion to dismiss BDSI’s appeal. On September 30, 2019, BDSI filed a petition for rehearing in the Federal Fourth Circuit Court *en banc*, which we opposed. The Federal Fourth Circuit Court denied BDSI’s petition for rehearing *en banc* on January 13, 2020. After the Federal Fourth Circuit Court denied BDSI’s petition, on January 13, 2020, BDSI filed with the Eastern District of North Carolina Court a motion to dismiss the Complaint, and we opposed on February 2, 2020. The Eastern District of North Carolina Court denied BDSI’s motion to dismiss on April 1, 2020. On April 16, 2020, BDSI filed an Answer to the Complaint, including counterclaims for non-infringement, invalidity, and unenforceability of the ’167 patent. Our response to BDSI’s counterclaims is due May 7, 2020.

### **Antitrust Litigation**

On September 22, 2016, forty-one states and the District of Columbia, or the States, brought suit against Indivior and us in the U.S. District Court for the Eastern District of Pennsylvania, alleging violations of federal and state antitrust statutes and state unfair trade and consumer protection laws relating to Indivior’s launch of Suboxone Sublingual Film in 2010 and seeking an injunction, civil penalties, and disgorgement. After filing the suit, the case was consolidated for pre-trial purposes with the *In re Suboxone (Buprenorphine Hydrochloride and Naloxone) Antitrust Litigation*, MDL No. 2445, or the Suboxone MDL, a multidistrict litigation relating to putative class actions on behalf of various private plaintiffs against Indivior relating to its launch of Suboxone Sublingual Film. While we were not named as a defendant in the original Suboxone MDL cases, the action brought by the States alleges that we participated in an antitrust conspiracy with Indivior in connection with Indivior’s launch of Suboxone Sublingual Film and engaged in related conduct in violation of federal and state antitrust law. We moved to dismiss the States’ conspiracy claims, but by order dated October 30, 2017, the Court denied our motion to dismiss. We filed an answer denying the States’ claims on November 20, 2017. The fact discovery period closed July 27, 2018, but the parties agreed to conduct certain fact depositions in August 2018. The expert discovery phase closed May 30, 2019, but additional reports and depositions were conducted through August 1, 2019. *Daubert* briefing is ongoing. The remainder of the case schedule, including summary judgment briefing, is stayed pending resolution of Indivior’s appeal of the District Court’s class certification ruling in a co-pending multi-district litigation to which we are not a party. We are not able to determine or predict the ultimate outcome of this proceeding or provide a reasonable estimate, or range of estimates, of the possible outcome or loss, if any, in this matter.



## **California Complaint**

On December 5, 2019, Neurelis Inc. (“Neurelis”) filed a complaint against Aquestive in the Superior Court of California, County of San Diego alleging Unfair Competition, Defamation, and Malicious Prosecution related to the Company’s pursuit of FDA approval for Libervant™. Neurelis filed a First Amended Complaint on December 9, 2019, alleging the same three causes of action. The Company filed a Motion to Strike Neurelis’s Complaint under California’s anti-SLAPP (“strategic lawsuit against public participation”) statute on Friday, January 31, 2020, which Neurelis is expected to oppose. Neurelis filed a motion for leave to file a Supplemental Complaint on February 5, 2020, which we will oppose. A hearing on our anti-SLAPP motion and Neurelis’s motion for leave was scheduled for April 24, 2020 but was postponed as a result of court closures in San Diego County, California resulting from the COVID-19 pandemic. The parties are awaiting further action from the court regarding a new hearing date. We are not able to determine or predict the ultimate outcome of this proceeding or provide a reasonable estimate, or range of estimates, of the possible outcome or loss, if any, in this matter.

### **Note 19. Subsequent Event**

#### ***Federal Paycheck Protection Loan***

On April 17, 2020, the Company was awarded a loan under the federal Paycheck Protection Program (“PPP”) created under the CARES Act in response to the global COVID-19 pandemic. The Company received a \$4.8 million loan (the “PPP Loan”) which carried a 1% interest rate payable in 2.5 years. On April 23, 2020, the U.S. Small Business Administration issued revised guidelines which we view as establishing a strong presumption that publicly traded companies are not eligible to receive funding under the PPP. Despite qualifying under the PPP program rules and having been granted the loan, given the revised guidance and the implications of possibly not meeting changing criteria for qualification, we returned our PPP Loan on May 4, 2020.

## Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

*You should read this section in conjunction with our unaudited condensed interim consolidated financial statements and related notes included in Part I Item 1 of this Quarterly Report on Form 10-Q and our audited consolidated financial statements and related notes thereto and management's discussion and analysis of financial condition and results of operations for the years ended December 31, 2019 and 2018, respectively, included in our 2019 Annual Report on Form 10-K. All dollar amounts are in thousands except for share data.*

### Forward-Looking Statements

This Quarterly Report on Form 10-Q and certain other communications made by us include forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as “believe,” “anticipate,” “plan,” “expect,” “estimate,” “intend,” “may,” “will,” or the negative of those terms, and similar expressions are intended to identify forward-looking statements.

These forward-looking statements may include, but are not limited to, statements regarding therapeutic benefits and plans and objectives for regulatory approvals of AQST-108, Libervant™ and our other product candidates; ability to obtain FDA approval and advance AQST-108, Libervant and our other product candidates to the market; statements about our growth and future financial and operating results and financial position, regulatory approval and pathways, clinical trial timing and plans, our and our competitors' orphan drug approval and resulting drug exclusivity for our products or products of our competitors; short-term and long-term liquidity and cash requirements, cash funding and cash burn, business strategies, market opportunities, and other statements that are not historical facts. These forward-looking statements also are subject to the uncertain impact of the COVID-19 global pandemic on our clinical trials including site initiation, patient enrollment and timing and adequacy of clinical trials, on regulatory submission and regulatory reviews and approvals of our product candidates; pharmaceutical ingredient and other raw materials; on supply chain, manufacture and distribution and sale of and demand of our products and our liquidity and availability of capital resources; customer demand for our products and services; customers' ability to pay for goods and services; and ongoing availability of an appropriate labor force and skilled professionals.

These forward-looking statements are based on our current expectations and beliefs and are subject to a number of risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. Such risks and uncertainties include, but are not limited to, risks associated with the Company's development work, including any delays or changes to the timing, costs and success of our product development activities and clinical trials and plans; risk of delays in FDA approval of Libervant and our other drug candidates or failure to receive approval; risk of our ability to demonstrate to the FDA “clinical superiority” within the meaning of the FDA regulations of our drug candidate Libervant relative to FDA-approved diazepam rectal gel and nasal spray products including by establishing a major contribution to patient care within the meaning of FDA regulations relative to the approved products and there can be no assurance that we will be successful; risk that a competitor obtains FDA orphan drug exclusivity for a product with the same active moiety as any of our other drug products for which we are seeking FDA approval and that such earlier approved competitor orphan drug blocks such other product candidates in the U.S. for seven years for the same indication; risk inherent in commercializing a new product (including technology risks, financial risks, market risks and implementation risks and regulatory limitations); risk of development of our sales and marketing capabilities; risk of legal costs associated with and the outcome of our patent litigation challenging third-party at risk generic sale of our proprietary products; risk of sufficient capital and cash resources, including access to available debt and equity financing and revenues from operations, to satisfy all of our short-term and longer-term cash requirements and other cash needs, at the time and in the amounts needed; risk of failure to satisfy all financial and other debt covenants and of any default; risk-related to government claims against Indivior for which we license, manufacture and sell Suboxone® and which accounts for the substantial part of our current operating revenues; risk associated with Indivior's cessation of production of its authorized generic buprenorphine naloxone film product, including the impacted from loss of orders for the authorized generic product and risk of eroding market share for Suboxone and risk of sunseting product; risks related to the outsourcing of certain sales, marketing and other operational and staff functions to third parties; risk of the rate and degree of market acceptance of our product and product candidates; the success of any competing products, including generics; risk of the size and growth of our product markets; risks of compliance with all FDA and other governmental and customer requirements for our manufacturing facilities; risks associated with intellectual property rights and infringement claims relating to the Company's products; risk of unexpected patent developments; the impact of existing and future legislation and regulatory provisions on product exclusivity; legislation or regulatory actions affecting pharmaceutical product pricing, reimbursement or access; claims and risks that may arise regarding the safety or efficacy of the Company's products and product candidates; risk of loss of significant customers; risks related to legal proceedings including patent infringement, investigative and antitrust litigation matters; changes in government laws and regulations; risk of product recalls and withdrawals; uncertainties related to general economic, political, business, industry, regulatory and market conditions and other unusual items; and other uncertainties affecting the Company described in the “Risk Factors” section and in other sections included in our Annual Report on Form 10-K, in our Quarterly Reports on Form 10-Q, and in our Current Reports on Form 8-K filed with the Securities Exchange Commission (SEC). Given those uncertainties, you should not place undue reliance on these forward-looking statements, which speak only as of the date made. All subsequent forward-looking statements attributable to us or any person acting on our behalf are expressly qualified in their entirety by this cautionary statement. The Company assumes no obligation to update forward-looking statements, or outlook or guidance, after the date of this Quarterly Report on Form 10-Q whether as a result of new information, future events or otherwise, except as may be required by applicable law. Readers should not rely on the forward-



looking statements included in this Quarterly Report on Form 10-Q as representing our views as of any date after the date of the filing of this Quarterly Report on Form 10-Q.

## Overview

We are a pharmaceutical company focused on developing and commercializing differentiated products which leverage our proprietary PharmFilm® technology to solve patients' therapeutic problems and to meet patients' unmet medical needs. We have three commercial products, including one proprietary product and two out-licensed products, another FDA-approved product that has been out-licensed for commercialization in European markets following applicable regulatory approvals, as well as a late-stage proprietary product pipeline focused on the treatment of central nervous system, or CNS, diseases and an earlier stage pipeline including treatment of anaphylaxis. We believe that our products address the characteristics of these patient populations and the shortcomings of available treatments create opportunities for the development and commercialization of meaningfully differentiated medicines.

Sympazan® (clobazam), an oral film for the treatment of seizures associated with a rare, intractable form of epilepsy known as Lennox-Gastaut syndrome, or LGS, was approved by the FDA on November 1, 2018. The Company commercially launched Sympazan in December 2018. Sympazan was launched as a precursor and complement to our product candidate Libervant and continues to progress on key performance metrics including prescriber growth, repeat prescribers, quarterly growth in retail shipments, and covered lives.

Exservan®, utilizing our proprietary PharmFilm® technology, has been developed for the treatment of amyotrophic lateral sclerosis (ALS). Exservan was approved by the FDA on November 22, 2019. During the 2019 fourth quarter, we announced the granting of a license to Zambon S.p.A. for the development and commercialization of Exservan Oral Film in the European Union (EU) for treatment of ALS. Zambon is exclusively responsible for obtaining regulatory approval and marketing Exservan in the EU, and we have sole and exclusive manufacturing rights for the product in the EU. We are seeking an appropriate licensee for the commercialization rights for Exservan in the United States. There can be no assurance that we will be successful in licensing Exservan in the United States.

Our most advanced proprietary investigational product candidate, which we intend to self-commercialize, subject to FDA approval for market access in the U.S., is Libervant.

Libervant is a buccally, or inside of the cheek, administered soluble film formulation of diazepam. Aquestive is developing Libervant as an alternative to the historical device-dependent standard of care rescue therapy for patients with refractory epilepsy, which is a rectal gel. As a result of this route of administration, a large portion of the patient population has not received adequate treatment or has forgone treatment altogether. We believe that Libervant, if approved by the FDA, will enable a larger share of these patients to receive treatment by providing a non-invasive and innovative treatment form for epileptic seizures. The Company filed an NDA for Libervant in November 2019 and the FDA has assigned a Prescription Drug User Fee Act (PDUFA) goal date of September 27, 2020. A competitive nasal spray product with orphan drug exclusivity was approved in January 2020. We continue to engage in the normal course of business interactions, inclusive of responding to information requests, with the FDA ahead of the September PDUFA date. We will seek to demonstrate that Libervant will, if approved by the FDA for marketing access in the U.S., represent a "major contribution to patient care" within the meaning of FDA regulations and guidance, as compared to available treatment options, as the first orally non-device delivered diazepam-based product available to manage seizure clusters in epilepsy patients. However, overcoming the orphan drug marketing exclusivity is difficult to establish, with limited precedent, and there can be no assurance that the FDA will agree with our position and approve Libervant for market access in the U.S.

We have also developed a proprietary pipeline of complex molecule-based products addressing market opportunities beyond CNS indications, which include:

- AQST-108, a "first of its kind" oral sublingual film formulation delivering systemic epinephrine that is in development for the treatment of anaphylaxis using Aquestive's proprietary PharmFilm® technologies. Epinephrine is the standard of care in the treatment of anaphylaxis and is currently administered via subcutaneous or intramuscular injection. The current market leader is EpiPen®, a single-dose, pre-filled automatic injection device. As a result of its administration via subcutaneous or intra-muscular injection, many patients and their caregivers are reluctant to use currently available products, resulting in increased hospital visits and overall cost of care to treat anaphylactic events. The data from the previously completed Phase I dose escalation study demonstrated that AQST-108 achieved similar ranges of mean values of maximum concentration (C<sub>max</sub>) and time to reach maximum concentration (T<sub>max</sub>) to that reported for injectables EpiPen and Auvi-Q®, provided a greater total exposure (AUC<sub>0-t</sub>; area under the curve) than that reported for EpiPen and Auvi-Q, had less interpatient variability when compared to degree of variation (CV%) data reported for EpiPen and another injection device, Auvi-Q, and was well tolerated, with no study participants discontinuing participation due to an adverse event. We believe that, as a result of its sublingual administration, AQST-108 will improve patient compliance and lower the total cost of care. After a constructive face-to-face pre-IND meeting with FDA in early February 2020, the Company is in the process of preparing the IND for AQST-108 expected to be submitted to the FDA in late June 2020, subject to any delays resulting from the COVID-19 pandemic. The FDA confirmed that the drug candidate will be reviewed under the 505(b)(2) regulatory approval pathway, and that no additional studies will be necessary prior to opening the proposed IND application. We expect to begin PK clinical trials later in 2020, subject to any delays resulting from the COVID-19 pandemic.

- AQST-305 is a sublingual film formulation of octreotide, a small peptide that has a similar pharmacological profile to natural somatostatin, for the treatment of acromegaly, as well as severe diarrhea and flushing associated with carcinoid syndrome. Acromegaly is a hormone disorder that results from the overproduction of growth hormone in middle-aged adults. Octreotide is the standard of care for the treatment of acromegaly. The current market leader, Sandostatin®, is administered via deep subcutaneous or intramuscular injections once a month. This monthly treatment regimen can result in loss of efficacy toward the end of the monthly treatment cycle. We are developing AQST-305 as a non-invasive, pain-free alternative to Sandostatin to reduce treatment burden, healthcare costs and the potential loss of efficacy of the treatment cycle. AQST-305 has shown promising preclinical results. We have completed an initial human proof of concept study, and we are further optimizing the formulation.

The COVID-19 pandemic may adversely impact the expected timelines for our clinical trials and studies and could contribute to delay in obtaining regulatory review and approval for our product candidates.

In addition to these product candidates, we have a portfolio of commercialized and development-stage licensed products. Our largest commercialized licensed product to date is Suboxone, a sublingual film formulation of buprenorphine and naloxone, for the treatment of opioid dependence. We have a sole and exclusive worldwide manufacturing agreement with Indivior to deliver Suboxone.

In early 2019, certain third-party pharmaceutical companies launched, at risk, generic film products for buprenorphine-naloxone. Also, in early 2019, Indivior, through Sandoz Inc. (“Sandoz”), began to market and sell an authorized generic sublingual film product for Suboxone, which we also exclusively manufactured and supplied. On October 15, 2019, Indivior publicly announced that, in order to mitigate the impact from the recent passage of H.R. 438- Continuing Appropriations Act, 2020, and Health Extenders Act of 2019, which came into effect on October 1, 2019, and which includes changes to the methodology for calculating average manufacturer price for branded drugs, Indivior had given notice to Sandoz of Indivior’s intention to cease production of the authorized generic sublingual film product. As of mid-April 2020, Suboxone branded products retain approximately 40% of film market share. Indivior accounted for 79% and 88% of our total revenues for the three-month periods ended at March 31, 2020 and 2019, respectively. Our total revenue mix is expected to shift to a higher proportionate share of proprietary product sales in future years as we continue to grow Sympazan revenues and pursue the launch of other products in our pipeline, assuming FDA approval. While revenues are expected to decrease in 2020 for Suboxone, our manufacturing price for Suboxone increased in the first quarter of 2020 which is expected to positively impact gross margin contribution from manufacturing and supply revenue throughout the year.

We manufacture all of our licensed and proprietary products at our FDA- and DEA-inspected facilities and anticipate that our current manufacturing capacity is sufficient for commercial quantities of our products and product candidates currently in development. We have produced over 2 billion doses of Suboxone since 2006. Not all collaborative or licensed products of the Company that may be commercially launched in the future will necessarily be manufactured by the Company. Our products are developed using our proprietary PharmFilm® technology and know-how. The COVID-19 pandemic could negatively impact our continued commercialization of Sympazan, impact demand for our approved products and development and commercialization of other products in our pipeline.

The Company trades on the Nasdaq Global Market under ticker symbol “AQST” after having completed its initial public offering in July 2018.

On July 15, 2019, we completed a private placement of \$70,000 of 12.5% Senior Secured Notes due June 2025 (“Notes or Senior Secured Notes”) and warrants for the purchase of up to 2 million common shares, against which 428,571 common shares were issued in December 2019 upon exercise. The new financing provided net proceeds of \$66,056 after expenses. The net proceeds of the financing were used to repay all outstanding obligations under the Company’s prior credit facility of \$52,944. We used the remaining net cash proceeds of \$13,110 for the continued commercialization and advancement of our proprietary products and pipeline candidates, and other general corporate purposes. Our Notes are discussed in Note 13, 12.5% Senior Secured Notes, to our condensed consolidated financial statements included herein and in Liquidity and Capital Resources.

On September 11, 2019, we filed with the SEC a Registration Statement on Form S-3, which was declared effective on September 17, 2019 (File No. 353-233716) (the “S-3 Registration Statement”). Under the S-3 Registration Statement we may sell up to \$150 million of our securities including, without limitation, common stock, preferred stock, warrants, and debt securities. On September 11, 2019, we entered into an equity distribution agreement to offer shares of our common stock from time to time in an “at-the-market” offering. We may offer and sell shares of common stock for an aggregate offering price of \$25.0 million. No shares have been sold pursuant to this “at-the-market” offering as of the date of this report. The agreement does not have an expiration date but can be canceled by us at any time for convenience with 10 days written notice. On December 12, 2019, we sold 8,050,000 common shares for gross proceeds of \$40,250 in an underwritten public offering under the S-3 Registration Statement, that netted \$37,295 after the underwriter discount and offering costs. We have also reserved under the S-3 Registration Statement up to an additional 4,222,082 shares of our common stock for sale by our stockholders and for the exercise of warrants held by the holders of our 12.5% Senior Secured Notes. Under our S-3 Registration Statement we are subject to, among other requirements applicable to our continuing eligibility to offer and sell securities pursuant to that short-term registration statement, the “baby shelf” registration requirements which may limit the amounts available under the registration statement if its public float falls below certain minimum levels at the time of filing our Annual Report on 10-K. At this time, the Company is not subject to any such limitation.

We generated revenue of \$8,765 and \$12,643 for the three months ended March 31, 2020 and 2019, respectively, largely from manufacturing and supply revenues from commercial products licensed to our collaboration or commercialization licensees. Total revenues also included licensing, royalty and co-development and research fees and our proprietary product sales. Our licensed revenue is subject to the normally uneven nature of the timing of co-development and licensing milestone payments, and to the volumes of product our licensees sell on the market from which we receive royalties and manufacturing revenues. Suboxone, which was launched in 2010, was our first licensed pharmaceutical product to be commercialized, and we have other licensing relationships that contribute to our revenue and future revenue opportunities. Sympazan, which was launched in December 2018, is the first proprietary pharmaceutical product commercialized directly by the Company. As of March 31, 2020, we had \$35,521 in cash and cash equivalents. As a result of our investments in product development, recent investments in commercialization initiatives and share-based compensation expenses surrounding the 2018 initial public offering, among other expenses, as of March 31, 2020, we had an accumulated deficit of \$147,004 resulting in a net shareholders’ deficit of \$20,829 as of that date. For the three months ended March 31, 2020 and 2019, we incurred net losses of \$16,530 and \$14,726, respectively.

We expect to continue to incur net losses for at least the next few years as we pursue the development, commercialization and marketing of our proprietary product candidates. Our net losses may fluctuate significantly from period to period, depending on regulatory approval developments concerning both our late-stage and earlier stage product candidates, the timing of our planned clinical trials and expenditures on our other research and development, as well as our commercialization activities. We expect our expenses will continue to be substantial in 2020 and future periods over time as we:

- Focus on the approval of Libervant for marketing in the U.S. and, subsequently, if approved, which we cannot assure, its commercialization,
- Continue to clinically develop AQST-108 along the 505(b)(2) pathway with PK clinical trials expected to begin in late 2020, subject to any delay as a result of the coronavirus pandemic, and
- Continue to grow Sympazan sales as a precursor and complement to the eventual launch of Libervant, if approved.

We will continue to manage the timing and level of expenses in light of the declining revenues related to Suboxone, offset in part by the revenue contribution from Sympazan, while focusing on the development and commercialization of Libervant and AQST-108, if approved.

Our business has been financed through a combination of revenue from licensed product and proprietary product activities, proceeds from our IPO, equity investments and other equity issuances and proceeds from our debt instruments and facilities. Significant additional funding is expected to be required in order to execute our business strategy and operations.

Until we become profitable, if ever, we expect to need to raise significant additional capital through equity or debt issuances, or both, in the future to further the development, regulatory approval, commercialization and marketing of our products and product candidates, and to conduct our business. We have no committed sources of additional capital, and there can be no assurance that such needed capital will be available on favorable terms, or at all. We have options to seek to obtain additional capital in the future through the issuance of our common stock, through other public or private equity or debt financings, through potential non-dilutive capital raising events that may result from royalty streams that may be realizable from our licensed products or licensed partnered intellectual property, and through collaborations or licensing arrangements with other companies or other means, if available. We may not be able to raise additional capital or other funding on terms acceptable to us, or at all, and any failure to raise capital as and when needed could compromise our ability to execute our business plan and cause us to delay or curtail our operations until such funding is received. To the extent that we raise additional funds by issuance of equity securities, our stockholders would experience dilution, and other debt financings, if available (and subject to all of the existing restrictions and conditions under the Indenture for the Senior Secured Notes) may involve increased restrictive covenants and increased fixed payments or may otherwise further constrain our financial flexibility. To the extent that we raise additional funds through collaborative or licensing arrangements, it may be necessary to relinquish some rights to our intellectual property or grant licenses on terms that are not favorable to us. In addition, payments made by potential collaborators or licensors generally will depend upon our achievement of negotiated development and regulatory milestones. Failure to achieve these milestones may harm our future capital position. See “Funding Requirements” below for Aquestive’s cash needs.



## **Business Update Regarding COVID-19**

The current COVID-19 pandemic has presented substantial health and economic risks, uncertainties and challenges to our business, the U.S. economy and financial markets. It is not currently possible to predict how long the pandemic will last or the time it will take for the economy to return to prior levels. The extent to which COVID-19 impacts our business, operations, clinical trials, regulatory approval process, financial results and financial condition, and those of our suppliers, distributors, customers and other third parties necessary to our business including those involved in the regulatory approval process, will depend on future developments, which are highly uncertain and cannot be predicted with certainty or clarity, including the duration and continuing severity of the outbreak, additional government actions to contain COVID-19, and new information that will emerge concerning the short-term and long-term impact.

To date, we have been able to continue to manufacture and supply our products and currently do not anticipate any interruption in supply, although we continue to monitor this situation closely and there is no assurance that disruptions or delays may not occur as a result of COVID-19. We are also monitoring demand for our products, which could be negatively impacted during the COVID-19 pandemic.

Our office-based employees have generally been working from home since mid-March 2020, while essential staffing levels in our operations remain on site, including key personnel in our laboratories and manufacturing locations. We have also suspended in-person interactions by our sales and marketing personnel and we are engaging remotely to support our commercialization efforts. We are currently expecting to commence our AQST-108 clinical trial in late 2020, although the COVID-19 precautions could directly or indirectly impact timelines, which we will continue to monitor and assess. For additional information on various uncertainties and risks posed by the COVID-19 pandemic, see Part II, Item 1A, Risk Factors included in this report.

### **Critical Accounting Policies and Use of Estimates**

See Note 3, *Summary of Significant Accounting Policies*, to our condensed consolidated financial statements, included herein for a discussion of recently issued accounting pronouncements and their impact or future potential impact on our financial results, if determinable. For a discussion of critical accounting policies that affect our judgments and estimates used in the preparation of our consolidated financial statements, refer to “*Critical Accounting Policies and Use of Estimates*” in our 2019 Annual Report on Form 10-K.

### **JOBS Act**

On April 5, 2012, the Jumpstart Our Business Startups Act, or the JOBS Act, was enacted. The JOBS Act provides that, among other things, an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. As an emerging growth company, we have elected to take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards and, as a result, we will comply with new or revised accounting standards not later than on the relevant dates on which adoption of such standards is required for emerging growth companies.

In addition, we intend to rely on the other exemptions and reduced reporting requirements provided by the JOBS Act. Subject to certain conditions set forth in the JOBS Act, as an “emerging growth company” we intend to rely on such exemptions and as a result, we are not required to, among other things, (i) provide an auditor’s attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act of 2002 and (ii) provide all of the compensation disclosure that may be required of non-emerging growth public companies under the Dodd-Frank Wall Street Reform and Consumer Protection Act, or (iii) disclose certain executive compensation-related items such as the correlation between executive compensation and performance and comparisons of the Chief Executive Officer’s compensation to median employee compensation. These exemptions will apply for a period of five years following the consummation of our IPO or until we no longer meet the requirements of being an emerging growth company, whichever is earlier.

We are also a “smaller reporting company,” meaning that we are not an investment company, an asset-backed issuer, or a majority-owned subsidiary of a parent company that is not a “smaller reporting company,” and have either: (i) a public float of less than \$250 million or (ii) annual revenues of less than \$100 million during the most recently completed fiscal year and (A) no public float or (B) a public float of less than \$700 million. As a “smaller reporting company,” we are subject to reduced disclosure obligations in our SEC filings compared to other issuers, including with respect to disclosure obligations regarding executive compensation in our periodic reports and proxy statements and certain reduced financial disclosures in our periodic reports.

## Financial Operations Overview

### Revenues

Our revenues to date have been earned from our product development pipeline, marketed product activities and self-developed medicines. These activities generate revenues in four primary categories: manufacturing and supply revenue, co-development and research fees, license and royalty revenue, and proprietary product sales, net.

#### *Manufacture and Supply Revenue*

Currently, we produce two licensed commercialized pharmaceutical products: Suboxone and Zuplenz. We are the exclusive manufacturer for these products. We manufacture based on receipt of purchase orders from our licensees, and our licensees have an obligation to accept these orders once quality assurance validates the quality of the manufactured product. Under ASC 606, we record revenues once the manufactured product passes quality control inspections. Our licensees are responsible for all other aspects of commercialization of these products and the Company has no role in or ability to participate in commercialization including marketing, pricing, sales and regulatory strategy.

We expect future manufacture and supply revenue from licensed products to be based on volume demand for such licensed products and manufacturing and supply rights under new collaborations for product development and additional licensing of our intellectual property.

#### *Co-development and Research Fees*

We work with our licensees to co-develop pharmaceutical products. In this regard, we earn fees through performance of specific tasks, activities, or completion of stages of development defined within a contractual arrangement with the relevant licensee. The nature and extent of these performance obligations, broadly referred to as milestones or deliverables, are usually dependent on the scope and structure of the project as contracted, as well as the complexity of the product and the specific regulatory approval path necessary for that product.

#### *License and Royalty Revenue*

Once a viable product opportunity is identified from our co-development and research activities, including with our licensees, we may out-license to our licensees the rights to utilize our intellectual property related to their marketing of such products. As a result, we earn revenue from license fees received under such license, development and supply agreements. We also may earn royalties based on our licensees' sales of products that use our intellectual property that are marketed and sold in the countries where we have patented technology rights.

#### *Proprietary Product Sales*

As we commercialize our proprietary CNS product candidates for which we receive regulatory approval to market such product beginning with Sympazan, we may directly sell such product to consumers in the United States, resulting in an additional source of revenue which we refer to as proprietary product sales. We commercialized our first proprietary CNS product, Sympazan, in December 2018. We currently sell Sympazan through wholesalers for distribution through retail pharmacies. Additionally, we may choose to select a collaborator to commercialize our product candidates in certain markets outside of the United States. To date, the only revenue generated from our self-developed and self-commercialized pharmaceutical products is from the sale of Sympazan in the United States.

Revenues from sales of products are recorded net of prompt payment discounts, wholesaler service fees, returns allowances, rebates and co-pay support redemptions, each of which are described in more detail below. These reserves are based on estimates of the amounts earned or to be claimed on the related sales. These amounts are treated as variable consideration, estimated and recognized as a reduction of the transaction price at the time of the sale. The Company records these estimated amounts in connection with the transaction price to the extent it is probable that a significant reversal of cumulative revenue recognized for such transaction will not occur, or when the uncertainty associated with the variable consideration is resolved. The calculation of some of these items requires management to make estimates based on sales data, historical return data, contracts and other related information that may become known in the future. The adequacy of these provisions is reviewed on a quarterly basis.



### *Prompt Pay Discounts*

The prompt pay reserve is based upon discounts offered to wholesalers as an incentive to meet certain payment terms. We accrue discounts to wholesalers based on contractual terms of agreements. We account for these discounts at the time of sale as a reduction to gross product sales and a reduction to accounts receivable.

### *Wholesaler Service Fees*

Our customers include major and regional wholesalers with whom we have contracted a fee for service based on a percentage of gross product sales. This fee for service is recorded as a reduction to gross product sales and an increase to accrued expenses at the time of sale and is recorded based on the contracted percentage.

### *Returns Allowances*

We allow customers to return product that is damaged or received in error. In addition, we allow Sympazan to be returned beginning six months prior to and twelve months following product expiration. We estimate our sales returns reserve based on industry averages until which time we have accumulated enough data to apply a historical trend analysis. The returns reserve is recorded at the time of sale as a reduction to gross product sales and accounts receivable.

### *Rebates*

Rebates include third-party managed care, Medicaid and Medicare Part D rebates, and other government rebates. Rebates are accrued based upon an estimate of claims to be paid for product sold into trade by the Company. The provisions for government rebates were based on contractual terms and government regulations. We monitor legislative changes to determine what impact such legislation might have on our Company. We account for these deductions as a reduction of gross products sales and an increase in accrued expenses.

### *Co-Pay Support Programs*

Co-pay support costs represent the costs to help offset a customer's co-pay or cover a predetermined amount of prescription based on business rules. We account for these deductions as a reduction of gross product sales and an increase in accrued expenses.

### ***Costs and Expenses***

Our costs and expenses are primarily the result of the following activities: generation of manufacture and supply revenues; development of and the regulatory approval process for our pipeline of proprietary product candidates; and selling, general and administrative expenses, including pre-launch and post launch commercialization efforts related to our CNS product candidates, intellectual property procurement, protection, prosecution and litigation expenses, corporate management functions, public company costs, share-based compensation expenses and interest on our corporate borrowings. We primarily record our costs and expenses in the following categories:

#### *Manufacture and Supply Costs and Expenses*

Manufacture and supply costs and expenses are comprised primarily of costs and expenses related to manufacturing our proprietary dissolving film products for our marketed licensed pharmaceutical products and for our newly approved proprietary products including raw materials, direct labor and fixed overhead principally in our Portage, Indiana facilities. Our material costs include the costs of raw materials used in the production of our proprietary dissolving film and primary packaging materials. Direct labor costs consist of payroll costs (including taxes and benefits) of employees engaged in production activities. Fixed and semi-fixed overhead principally consists of indirect payroll, facilities rent, utilities and depreciation for leasehold improvements and production machinery and equipment.

Our manufacture and supply costs and expenses are impacted by our customers' supply requirements. Costs of production reflect the costs of raw materials that are purchased at market prices and production efficiency (measured by the cost of a salable unit). These costs can increase or decrease based on the amount of direct labor and materials required to produce a product and the allocation of fixed overhead, which is dependent on the levels of production.



We will continue to seek to rationalize and reduce costs to reflect the declining production volumes of Suboxone. Our production cost of manufacturing and supply increased in late 2019 resulting from declining volume of Suboxone that began in 2019 and continues to decline in 2020. We expect our manufacture and supply costs and expenses to decrease over the next several years due to the decline in Suboxone volumes as the generics in that market continue to take market share, modestly offset by the commercialization of our proprietary products, starting with the launch of Sympazan in December 2018. In addition to our proprietary products coming online, we may add licensed products which may need additional resources to manufacture. If such growth should occur for higher volume product opportunities such as Suboxone we would incur increased costs associated with hiring additional personal to support the increased manufacturing and supply costs arising from higher manufactured volumes from proprietary and licensed products.

### *Research and Development Expenses*

Since our inception, we have focused significant resources on our research and development activities. Research and development expenses primarily consist of:

- employee-related expenses, including compensation, benefits, share-based compensation and travel expenses;
- external research and development expenses incurred under arrangements with third-parties, such as contract research organizations, investigational sites and consultants;
- the cost of acquiring, developing and manufacturing clinical study materials; and
- costs associated with preclinical and clinical activities and regulatory operations.

We expect our research and development expenses to continue to be significant over the next several years as we continue to develop existing product candidates such as AQST-108 and we expand our efforts to identify and develop or acquire additional product candidates and technologies. We may hire or engage additional skilled colleagues or third-parties to perform these activities, conduct clinical trials and ultimately seek regulatory approvals for any product candidate that successfully completes those clinical trials.

### *Selling, General and Administrative Expenses*

Selling, general and administrative expenses consist primarily of salaries, benefits, share-based compensation, commercialization and marketing costs, and other related costs for executive, finance, selling and operational personnel. Other significant costs include facility and related costs not otherwise included in research and development expenses such as: professional fees for legal, consulting, tax and accounting services; insurance; selling; market research; advisory board and key opinion leaders; depreciation; and general corporate expenses, inclusive of IT systems related costs.

Costs related to the commercialization of our CNS products began in the second half of 2017 and significantly increased in 2018 leading up to the launch of Sympazan in December 2018. Significant investments in commercialization were made in 2019. We will continue to invest in the commercialization of Sympazan in 2020 but those costs will be rationalized to the expected near-term opportunity Sympazan represents. In the later part of the year we would expect additional expenses to occur in order to launch Libervant should it be approved.

Sympazan is the precursor and compliment to the launch of Libervant if it is approved and granted access to market. There is a very high degree of overlap and correlation between prescribers of Sympazan and the likely prescribers of an approved Libervant. While Sympazan continues to grow, we will continue to rationalize its contribution as a product and its value as a way to introduce prescribers to the epilepsy market, to Aquestive and PharmFilm® technology and the investment we are making in this form of commercialization and marketing spend supporting it. The current commercial organization would launch Libervant, subject to its approval, without expecting to immediately add significant internal personnel costs although marketing and selling expenses will increase if Libervant is approved and ready to be marketed. Until any Libervant launch is clear, we do not plan to increase the costs of our commercial organization and will continue to improve the efficiency of the Sympazan commercial investments.

Our general and administrative costs increased after 2017 as a result of becoming a public company, including costs related to accounting, audit, legal, regulatory and tax-related services with maintaining compliance with exchange listing and SEC requirements, director and officer insurance costs, and investor and public relations costs. We continue to incur significant costs in seeking to protect our intellectual property rights, including significant litigation costs in connection with seeking to enforce our rights concerning third parties' at-risk launch of generic products.

We will continue to manage the business costs to appropriately reflect the declining Suboxone revenue, the marketing and sales costs related to Sympazan and other external factors affecting our business including the continuing impact of the COVID-19 pandemic, as we continue to focus on the core drivers of value to our stockholders:

- Seeking to obtain the approval and subsequent launch of Libervant, subject to approval for marketing in the U.S.;
- The continued, accelerated development of AQST-108 along the 505(b)(2) pathway with PK clinical trials expected to begin in late 2020, subject to any delays associated with the coronavirus pandemic; and
- Growing the revenue contribution from Sympazan as a first step to position Aquestive in the epilepsy community.

### Interest Expense

Interest expense consists of interest costs related to our debt facility, as well as amortization of loan costs and debt discount. Our interest cost, which under our Perceptive credit facility was subject to changes in one-month LIBOR, represented a monthly cash payment obligation. Our Senior Secured Notes are discussed in Note 13, 12.5% Senior Secured Notes, to our Condensed Consolidated Financial Statements and in Liquidity and Capital Resources. Interest expense has increased based on additional borrowings under such new Notes. Under the new facility, interest is fixed at 12.5% and is payable quarterly.

### Interest Income

Interest income consists of earnings derived from an interest-bearing account. There is no minimum amount to be maintained in the account nor any fixed length of period for which interest is earned.

## Results of Operations

### Comparison of the Three Months Ended March 31, 2020 and 2019

We recorded revenue of \$8,765 and \$12,643 in the three months ended March 31, 2020 and 2019, respectively, generating net losses of \$16,530 and \$14,726 for each of those periods, respectively.

### Revenues

	Three Months Ended		Change	
	2020	2019	\$	%
<i>(in thousands, except %)</i>				
Manufacture and supply revenue	\$ 6,916	\$ 6,669	\$ 247	4%
License and royalty revenue	426	4,622	(4,196)	(91%)
Co-development and research fees	263	770	(507)	(66%)
Proprietary product sales, net	1,160	582	578	99%
Revenues	\$ 8,765	\$ 12,643	\$ (3,878)	(31%)

For the three months ended March 31, 2020, total revenues decreased 31% or \$3,878 to \$8,765 compared to revenues of \$12,643 for the same period in 2019. The change is primarily attributable to decreases in license and royalty revenue and in co-development and research fees, offset in part by increase in manufacture and supply revenue and proprietary product sales revenue.

Manufacture and supply revenue increased approximately 4% or \$247 to \$6,916 for the three months ended March 31, 2020 compared to \$6,669 from the prior year period. This increase is attributable to increased pricing associated with our Suboxone product affecting the current period offset in part by 28% total lower volumes of Suboxone and the Suboxone authorized generic period over period. As discussed above, Indivior announced in the fourth quarter 2019 the cessation of the sale and marketing of the authorized generic, which has impacted our manufacturing and supply revenue in the three months ended March 31, 2020 and this decision will continue to impact revenues throughout 2020. The branded Suboxone products, currently holding approximately 40% of the film market, have continued to experience market share erosion as generic competition continues to take more market share following the U.S. court of appeals lifting a preliminary injunction in February 2019 allowing generic competitors into the U.S. Suboxone market “at risk” while patent infringement cases against those generic manufactures are tried to conclusion. We continue to plan for the further erosion of this sunseting product over time.

License and royalty revenue decreased 91% or \$4,196 to \$426 for the three months ended March 31, 2020 compared to revenues of \$4,622 from the prior year period. This change was primarily related to the timing of license and new patent fees on our licensed product Suboxone. The Company did not record any license fees from Indivior for the three months ended March 31, 2020 compared to \$4,250 of license fees recognized during the prior year comparative period. Suboxone related license fees were \$4,250 lower compared to 2019, primarily due to the fact that all license fees due from Indivior have been suspended pending the outcome of litigation related to infringement claims against the generic products launched “at risk.” Royalty revenues earned on Suboxone and Zuplenz remained relatively flat year-over-year. License fees are generally driven by transfer

of rights, patent performance contingencies, specific FDA or other regulatory achievements, sales levels achievements or other contingencies and milestones, and will likely fluctuate significantly from quarter-to-quarter.

Co-development and research fees decreased 66% or \$507 to \$263 for the three months ended March 31, 2020 compared to \$770 from the prior year period. The decrease was driven by the timing of the achievement of research and development performance obligations on research and development projects and related milestones and are normally expected to fluctuate significantly one reporting period to the next.

Proprietary product sales, net increased \$578 or 99% to \$1,160 for the three months ended March 31, 2020 compared to \$582 from the prior year period, due to increased Sympazan prescriptions written by CNS physicians and improved payor approval rates.

#### *Expenses and Other:*

	Three Months Ended		Change	
	March 31,		\$	%
	2020	2019		
<i>(in thousands, except %)</i>				
Manufacturing and supply	\$ 3,659	\$ 3,506	\$ 153	4%
Research and development	4,354	4,303	51	1%
Selling, general and administrative	14,613	17,908	(3,295)	(18%)
Interest expense	2,771	1,926	845	44%
Interest income	(102)	(274)	(172)	(63%)

Manufacturing and supply costs and expenses increased 4% or \$153 to \$3,659 for the three months ended March 31, 2020 compared to \$3,506 for the same period in 2019. This increase was primarily driven by higher standard product costs per unit offset in part by lower volume of Suboxone production.

Research and development expenses increased 1% or \$51 to \$4,354 for the three months ended March 31, 2020 compared to \$4,303 in the prior year period. Research and development expenses are driven primarily by the timing of clinical trial activities associated with the Company's pipeline.

Selling, general and administrative expenses decreased 18% or \$3,295 to \$14,613 for the three months ended March 31, 2020 as compared to \$17,908 for the prior year period. The decrease was from two primary areas: commercial expenses and unabsorbed factory overhead expenses. Commercial expenses are lower in the first quarter of 2020 by approximately \$2.2 million as the first quarter of 2019 included significant initial launch expenses for Sympazan that did not repeat in 2020, and from the company's efforts to manage costs and capital runway. Unabsorbed factory overhead expenses are lower by about \$2 million reflecting the company's efforts to reduce the costs of plant operations while production volumes decline as a result of Suboxone erosion. These reductions were partially offset by higher insurance premiums and share-based compensation expense.

Interest expense increased 44% or \$845 to \$2,771 for the three months ended March 31, 2020 as compared to \$1,926 for the same period in 2019. This is the result of \$20,000 of additional outstanding debt and related higher loan acquisition costs and debt discount associated with the issuance of our Senior Secured Notes. Prior to July 15, 2019, our interest expense was subject to fluctuations based on one-month LIBOR and was approximately 12% to 12.5%. Our new Senior Secured Notes due 2025 issued on July 15, 2019 carry a 12.5% fixed interest rate per annum.

Interest income decreased 63% or \$172 to \$102 for the three months ended March 31, 2020, compared to \$274 of interest income for the same period in 2019. This decrease is a result of investing lower net cash balance in the first quarter of 2020 compared to the same period in 2019.

## **Liquidity and Capital Resources**

### **Sources of Liquidity**

Since our inception in January 2004, we have incurred significant losses and as of March 31, 2020, we have a net stockholders' deficit of \$20,829. We have funded our operations primarily with equity and debt financings and milestone and royalty payments from our collaboration licensees and manufacturing and supply revenue.

We generate revenue from licensed products and proprietary product sales, net and related activities, but the costs to generate these revenues and the costs and expenses of our proprietary CNS and complex molecule development programs, related commercialization efforts and interest expenses have resulted in the \$147,004 deficit we have accumulated from inception.

We had \$35,521 in cash and cash equivalents as of March 31, 2020. We have no committed sources of capital.

### **Equity Offering**

On December 17, 2019, we completed an underwritten equity offering of 8,050,000 shares of common stock pursuant to our S-3 Registration Statement, including exercise of the underwriter's over-allotment option, resulting in gross proceeds of approximately \$40,250 before underwriter discounts and other costs and expenses and net proceeds were \$37,295.

### **12.5% Senior Secured Notes**

On July 15, 2019 we issued \$70,000 aggregate principal amount of our 12.5% Senior Secured Notes due 2025 ("Senior Secured Notes") and Warrants under the Indenture for such Senior Secured Notes ("Indenture"). In addition, the Indenture provides opportunity to issue up to \$30,000 of additional Notes under certain conditions for a total possible issuance amount of \$100,000.

The net proceeds from the Senior Secured Notes were \$66,054, after deducting expenses of the transaction. We used a portion of the net proceeds to repay an aggregate amount of \$52,092 of existing Perceptive indebtedness, comprised of the outstanding principal amount, all accrued and unpaid interest and applicable prepayment and end-of-term fees, owed to Perceptive under the Credit Agreement and Guaranty (described below). We used the remaining net cash proceeds of approximately \$13,110 for the continued commercialization and advancement of our proprietary products and pipeline candidates, and other general corporate purposes.

The additional Senior Secured Notes can be issued if we satisfy certain conditions and achieve certain milestones related to the filing approval of our epilepsy product candidate Libervant and there are available purchasers for the additional Senior Secured Notes. Specifically, on or prior to March 31, 2021, we have the option to issue an additional \$10,000 aggregate principal amount of the Senior Secured Notes if we filed a new drug application for our candidate Libervant with the FDA prior to that date, provided we have obtained the written consent of the holders of a majority in aggregate principal amount outstanding under the Notes, in their discretion, which cannot be assured (first reopener) and, on or prior to March 31, 2021, up to an additional \$30,000 (less the amount of any first reopener additional Senior Secured Notes issued by us) if the Company obtains approval from the FDA to market Libervant in the U.S. prior to that date. There can be no assurance that such additional financing will be consummated.

Interest on the Senior Secured Notes accrues at a rate of 12.5% per annum and is payable quarterly in arrears on March 30<sup>th</sup>, June 30<sup>th</sup>, September 30<sup>th</sup> and December 30<sup>th</sup> of each year commencing on September 30, 2019. On each payment date commencing on September 30, 2021, we will also pay an installment of principal of the Senior Secured Notes pursuant to a fixed amortization schedule. The stated maturity date of the Senior Secured Note is June 30, 2025.

Collateral for the loan consists of a priority lien on substantially all assets, including intellectual property, of the Company.

Under the Indenture, we have the right to monetize our royalty and milestone interests in our licensed product, Apomorphine APL-130277, which would not be expected prior to the anticipated May 21, 2020, FDA approval of the product. Upon any such monetization we are required to offer to purchase each holder's Notes on a pro rata basis at a repurchase price in cash equal to 112.5% of the principal amount of such Notes, plus accrued interest and unpaid interest, if any, thereon to the repurchase date. The maximum amount that can be offered for repurchase is \$40,000 or \$50,000 if the first reopener has been issued and funded. The amount of Senior Secured Notes repurchased will be at the discretion of the holders of a majority in aggregate principal amount outstanding under the Notes. See Note 13, 12.5% Senior Secured Notes, to our Condensed Consolidated Financial Statements. To the extent that the holders of the Note do not elect repayment of the debt in connection with any such monetization, the amount not elected up to \$40 million (or \$50 million if the first reopener has been funded) is required to be held in a collateral account until Libervant is approved by the FDA to be marketed in the U.S.

The Indenture permits us, upon the continuing satisfaction of certain conditions, including that we (on a consolidated basis) have at least \$75,000 of net revenues for the most recently completed twelve calendar month period, to enter into an asset-based borrowing facility ("ABL Facility") not to exceed \$10,000. The ABL Facility may be collateralized by assets constituting only inventory, accounts receivable and the proceeds thereof of the Company.

Affirmative and negative covenants and restrictions are specified in the Indenture considered typical for loans of this nature, including, but not limited to, requirements relating to preservation of corporate existence, publicly traded status, intellectual property and business interests; limitations or prohibitions of dividend payments or other distributions, repurchases of shares, asset transfers or dispositions, creation or occurrence of additional liens and security interests, and entering into licensing or monetization arrangements other than as permitted under the Indenture.

The Indenture also restricts the incurrence of additional indebtedness except only such indebtedness as is expressly permitted under the terms of the Indenture (which includes the ABL Facility) on the terms and conditions set forth in the Indenture and such indebtedness as may be permitted under limitations set forth in the Indenture. The Indenture also restricts the issuance of any “Disqualified Stock” including, generally, mandatorily redeemable securities or securities redeemable at the option of the holder or securities convertible or exchangeable at the option of the holder for indebtedness of the Company or for other Disqualified Stock.

In connection with this financing, we issued to the holders of the Notes, Warrants to purchase up to an aggregate of 2,000,000 share of common stock at a price of \$4.25 per Warrant. Warrants for 428,571 of common shares were exercised in December 2019 generating proceeds of \$1,829. The Company registered the Warrants and associated shares as part of our S-3 Registration. The were no Warrants exercised in the three-month period ended at March 31, 2020.

### **Credit Agreement and Guaranty**

On August 16, 2016, we entered into a Credit Agreement and Guarantee with Perceptive Credit Opportunities Fund (“Perceptive”), which we amended on May 21, 2018, or, as so amended, the Loan Agreement. At closing of the Loan Agreement, we borrowed \$45,000 under the Loan Agreement and were permitted to borrow up to an additional \$5,000 within one year of the closing date based on achievement of a defined milestone. In March 2017, we met our performance obligations under the terms of the Loan Agreement and received the remaining \$5,000 available to us under the Loan Agreement. Proceeds under the Loan Agreement were used to repay an existing debt obligation of \$37,500, with the balance available for general corporate purposes. The loan from Perceptive was originally scheduled to mature on August 16, 2020.

Upon the consummation of our IPO, the maturity date of the Loan Agreement was extended to December 16, 2020. The loan bore interest, payable monthly, at one-month LIBOR plus 9.75%, subject to a minimum rate of 11.75%. The loan was interest-only through April 2019, as amended.

Upon the closing of the IPO, Perceptive received 863,400 shares of common stock issuable pursuant to the automatic exercise of warrants from APL’s ownership interests for a total exercise price of \$116.

In July 2019, in connection with our issuance of our Senior Secured Notes (see above) we repaid all outstanding amounts due under the Loan Agreement.

### **Cash Flows**

#### **Three Months Ended March 31, 2020 and 2019**

(in thousands)

	<b>2020</b>	<b>2019</b>
Net cash (used for) operating activities	\$ (13,637)	\$ (17,680)
Net cash (used for) investing activities	(131)	(376)
Net cash (used for) financing activities	(37)	(2,609)
Net decrease in cash and cash equivalents	<u>\$ (13,805)</u>	<u>\$ (20,665)</u>

#### **Net Cash (Used for) Operating Activities**

Net cash used for operating activities for the three months ended March 31, 2020 was \$13,637. The use of cash can be understood as represented by three major factors: (1) our net loss of \$16,530, (2) decrease in operating assets and liabilities of \$294 partially offset by (3) non-cash operating expenses. The non-cash operating expenses of \$3,187 primarily resulted from \$1,860 of share-based compensation expense recorded in the first quarter of 2020. Other significant components included non-cash charges of \$1,327 related to non-cash charges such as depreciation, amortization and amortization of debt issuance costs.

Net cash used for operating activities for the three months ended March 31, 2019 was \$17,680. The use of cash can be understood as represented by three major factors: (1) our net loss \$14,726, (2) decrease in operating assets and liabilities of \$6,128 partially offset by (3) non-cash operating expenses. The non-cash operating expenses of \$3,174 primarily resulted from \$1,520 of share-based compensation expense recorded in the first quarter of 2019. Other significant components included non-cash charges of \$1,654 related to non-cash charges such as depreciation, amortization of debt issuance costs.



### ***Net Cash (Used for) Investing Activities***

Net cash used for investing activities was \$131 for the three months ended March 31, 2020 compared to \$376 for the three months ended at March 31, 2019. This decrease in net cash used for investing activities was primarily attributable to timing of capital expenditures for plant and equipment purchases.

### ***Net Cash (Used for) Financing Activities***

Net cash used for financing activities was \$37 for the three months ended March 31, 2020 compared to \$2,609 for the three months ended at March 31, 2019. The cash used in 2020 is a result of payment for withholding taxes on share-based compensation. The cash used in 2019 is a result of the payment of withholding taxes associated with tax reimbursement payments from the share-based compensation recorded during 2018.

### ***Funding Requirements***

We expect that our existing cash and cash equivalents combined with our anticipated revenue from our licensed product activities, including expected milestone payments, other co-development payments and royalty payments, manufacturing and supply revenues at anticipated levels, sales of our proprietary product at anticipated levels, cash on hand, and, subject to satisfaction of all conditions to and requirements for further issuances of our Senior Secured Notes, and assuming available purchasers thereof, potential additional proceeds from future issuances of up to \$30,000 of additional Senior Secured Notes, the net proceeds from our equity offering of common stock in December 2019, potential future monetization of certain royalty streams or other license rights for Apomorphine (subject to all conditions and requirements under the Senior Secured Notes Indenture and market conditions which may be impacted by the COVID-19 pandemic) and if needed and available to the Company, further access to the capital markets under our shelf registration statement filed with the SEC and declared effective September 17, 2019, will be adequate to fund our expected cash requirements for the next 12 months. We have based this expectation on assumptions that could change, or prove to be inaccurate, and additionally, we could utilize our available financial resources sooner than we currently expect.

In addition, the global coronavirus pandemic continues to rapidly evolve. The extent to which the coronavirus pandemic may impact our business, financial results, liquidity and potential cash resources will depend on future developments, which are highly uncertain and cannot be predicted with confidence.

The key assumptions underlying our funding expectations for the next 12 months include:

- current cash balances;
- continued revenue from our proprietary and licensed products at planned levels;
- our ability to monetize royalty streams or other license or proprietary rights for our product candidate Apomorphine at anticipated levels, which cannot be assured (and which is subject to conditions and requirements under the Indenture for our 12.5% Senior Secured Notes including note repurchase obligations at 112.5% of principal amount of such repurchased notes and accrued and unpaid interest thereon, at the option of the holders (see “12.5% Senior Secured Notes” above)) and which monetization would not be expected prior to FDA approval of this drug candidate;
- access to the capital markets if and at the time needed for any necessary future funding;
- continuing review of our cost structure and cost and expense reductions consistent with our anticipated revenues and funding;
- our ability to issue and assuming available purchasers of, additional Senior Secured Notes in an aggregate amount up to \$30,000 principal amount under the Indenture, based on satisfying certain conditions related to our Libervant product candidate which we cannot assure (see “12.5% Senior Secured Notes” above);
- continued funding of appropriate commercialization costs for Sympazan, our first proprietary product launched in December 2018 and continued funding of our development and, subject to FDA approval to market Libervant in the U.S., commercialization of our product candidate Libervant and our other proprietary product candidates;
- the infrastructure and administrative costs to support being a public company;
- continued compliance with all covenants under our Senior Secured Notes, and
- absence of significant unforeseen cash requirements.

We commercially launched our first proprietary product Sympazan in late 2018, and this product's net revenue continues to grow as expected. Because of the short duration of time since its initial launch, we currently spend more on commercialization costs than we receive in net revenue for Sympazan, and we expect this to be the case throughout 2020, the second full year after initial launch. Sympazan is our precursor to Libervant and enables the epilepsy and neurology community to become familiar with our Company and our PharmFilm® technology in advance of the anticipated launch of Libervant after approval by the FDA. For our commercialization efforts to continue to be successful we must continue to train, deploy and further develop an effective sales and marketing organization and infrastructure. To become and remain profitable we must continue to develop, obtain timely regulatory approval of, and successfully commercialize or otherwise out-license or monetize, those of our proprietary products and product candidates that we believe will have the most market potential and commercial success. We may encounter difficulties and delays in the regulatory approval process for our drug candidates, including Libervant, and our commercialization efforts may take longer to achieve than planned. Our business or operations may change and we may also encounter unanticipated or unbudgeted events or expenses that may require cash resources more rapidly than planned. We are unable to determine or forecast with certainty when or if we will achieve or sustain profitability. The uncertainties associated with the coronavirus pandemic increase these risks.

We will continue to manage business costs to appropriately reflect the declining state of Suboxone revenues, the marketing and sales costs related to Sympazan and other external factors affecting our business including the uncertainties associated with the coronavirus pandemic, as we continue to focus on the core drivers of value for our stockholders. We will continue to invest and devote financial resources to our ongoing product development activities in support of Libervant and AQST-108, research and development activities, pre-clinical activities, clinical trials, regulatory approval activities and commercialization activities. We will continue to seek to rationalize our costs as Suboxone revenue declines. Additionally, we will seek to conservatively manage our pre-launch spending as to both timing and level relating to Libervant, including seeking to rationalize the costs associated with marketing and selling Sympazan. In this regard, absent spending on launch activities for Libervant we expect to spend less on commercialization in 2020 compared to 2019. Even as such, we expect to continue to incur losses and negative cash flows and therefore we expect to be dependent upon external financing and funding to achieve our operating plan.

Our cash resources on hand are not sufficient by themselves to fund our expected development, commercialization and other operations and activities, and we expect to continue to require external sources of funding and capital to develop and seek regulatory approval of our product candidates and for the commercialization of our approved products. The amount and timing of our future requirements, both short-term and long-term, will depend on many factors, including:

- Our ability to achieve successful commercialization growth of our proprietary product Sympazan and the cost and timing of our future commercialization activities;
- Continued revenues at planned levels from our manufacture and sale of branded Suboxone to Indivior and continued market acceptance of such branded product, without any sales of the authorized generic version of Suboxone;
- Sunovion Pharmaceuticals, Inc ("Sunovion"), to whom we out-licensed our technology, achieving regulatory approval of Apomorphine on May 21, 2020 which is expected to provide the opportunity for a significant non-dilutive capital source for us;
- Achieving U.S. marketing regulatory approval in the time period we have anticipated of our product candidate Libervant which has been part of our business plan and strategy. We completed the filing of our NDA for Libervant with the FDA in the fourth quarter of 2019, and the FDA has granted a PDUFA goal date of September 27, 2020, although there can be no assurance we will obtain such approval;
- Continuing significant costs in seeking to protect our intellectual property rights, including significant litigation costs in connection with seeking to enforce our rights concerning third parties' at-risk launch of generic products;
- Patient and doctor acceptance of and our ability to obtain adequate reimbursement for our products which we commercialize;
- The effect of competing products, including generic products, on our commercialized and licensed products, including Suboxone;
- All other costs of executing our business plan and absence of unforeseen cash requirements; and
- The risks and uncertainties associated with the coronavirus pandemic.



The sufficiency of our short-term and longer-term liquidity is directly impacted by our level of operating revenues and our ability to achieve our operating plan for revenues, regulatory approval in the time period planned of our late-stage proprietary products and our ability to monetize in the time planned our royalty streams or other license rights such as Apomorphine. We also are entitled to further potential milestones, royalty and other payments under our Indivior Supplemental Agreement, which are suspended and may only be reinstated if Indivior successfully adjudicates or settles the related patent infringement litigation, and there is no assurance when or if any such payments may be due. Our operating revenues have fluctuated in the past and can be expected to fluctuate in the future. We expect to incur significant operating losses and negative cash flows for the foreseeable future, and we have a significant level of debt on which we have substantial ongoing debt repayment and debt service obligations. A substantial portion of our current and past revenues has been dependent upon our licensing, manufacturing and sales with one customer, Indivior, which is expected to continue while we commercialize our own proprietary products and it could take significantly longer than planned to achieve anticipated levels of cash flows to help fund our operations and cash needs from sales of our proprietary products other than Suboxone.

Management will continue to monitor the Company's cash requirements and liquidity, including expected revenue from manufacture and supply sales and proprietary sales, expected license and milestone revenues, any available proceeds from any monetization of royalty streams or other license rights, any future potential issuances of additional Senior Secured Notes under the Indenture, reduction in cash spend, net proceeds of future equity financing, if needed and available to it, which cannot be assured, or other future access to the capital markets under our shelf registration statement filed with the SEC and effective September 17, 2019 or other potential available sources of liquidity and, if management believes operating results and the above funding sources are not sufficient or available for existing or projected cash requirements, management will seek to take further steps intended to improve the Company's financial position and liquidity, such as by modifying our operating plan, adjusting the timing and scope of our development activities, seeking to further reduce costs and adjusting cash spend and evaluating and pursuing other potential opportunities to obtain additional liquidity.

Unless and until we become profitable, we will continue to need to raise additional capital and/or other financing or funding, any of which could be material, to further advance the development of our other product candidates, most importantly Libervant and AQST-108, which are subject to regulatory approval, and commercialization of our product candidates and to meet our other cash requirements, including debt service. We do not currently have any committed external sources of financing.

Our ability to secure additional equity financing could be significantly impacted by numerous factors including our operating performance and prospects, positive or negative developments in the regulatory approval process for our proprietary products, timely achievement of regulatory approval of our late-stage proprietary products, our existing level of debt which is secured by substantially all our assets, restriction under our Senior Secured Note Indenture, and general market conditions, and there can be no assurance that we will continue to be successful in raising capital or that any such needed financing will be available, available on favorable or acceptable terms or at the times or in the amounts needed. Additionally, while the potential economic impact brought on by and the duration of the coronavirus pandemic is difficult to assess or predict, the significant impact of the coronavirus pandemic on the global financial markets, and on our own stock trading price, may reduce our ability to access additional capital, which would negatively impact our short-term and longer-term liquidity.

We may also seek to obtain additional funding in the future through the monetization of royalty streams from our product Apomorphine, subject to regulatory approval thereof, which product candidate is licensed to Sunovion Pharmaceuticals, Inc. (and subject to the conditions and requirements under the Indenture for our 12.5% Senior Secured Notes including our note repurchase obligations at the option of the holders), but we cannot assure of any such royalty streams or monetization.

Our ability to obtain any additional indebtedness or other debt financing is limited by the terms of the Indenture and the Indenture also restricts or prohibits certain types of equity financing (see "12.5% Senior Secured Notes" above). To the extent we are able to obtain needed funding through additional debt financing, any such debt financing may be coupled with an equity component, such as warrants for our shares, which could also result in dilution to our stockholders. The incurrence of additional debt would also result in increased fixed payment obligations.

We may also seek to obtain additional funding through third-party funding, marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or any combination of these approaches. We may not be able to raise additional capital or other funding on terms acceptable to us, or at all, and any failure to raise additional capital or other funding as and when needed for our cash requirements would have a negative impact on our business prospects and financial condition and our ability to execute and achieve our business plan and cause us to delay or curtail our operations until such funding is received.

To the extent that we raise additional funds by issuance of equity securities, our stockholders would experience further dilution and the terms of these securities could include liquidation or other preferences (if and to the extent permitted under the Indenture) that would adversely affect our stockholders' rights. To the extent that we raise additional funds through collaborative, strategic alliances or licensing arrangements with third -parties, it may be necessary to relinquish (subject to required consent under our Indenture for the disposition or transfer of assets other than Apomorphine) valuable rights to our intellectual property or future revenue or grant licenses on terms that are not favorable to us or that we may not otherwise consider relinquishing or granting, including rights to future product candidates. In addition, payments made by potential collaborators or licensors generally will depend upon our achievement of negotiated development and regulatory milestones. Failure to achieve these milestones may harm our future liquidity and funding position.



If adequate funds are not available for our short-term or longer-term liquidity needs and cash requirements as and when needed, we may be required to reduce staff, delay, significantly scale back, or even discontinue some or all of our research and development programs and clinical and other product development activities, or reduce our planned commercialization efforts and otherwise significantly reduce our other spend and adjust our operating plan, and we would need to seek to take other steps intended to improve our liquidity. We also may be required to evaluate additional licensing opportunities, if any become available, of our proprietary product candidate programs that we currently plan to self-commercialize or explore other potential liquidity opportunities or other alternative or options or strategic alternatives, although we cannot assure that any of these actions would be available or available on reasonable terms.

Our costs associated with operating as a new public company have increased, and we expect to incur additional costs to support the obligation of a public company to various regulatory agencies, to investors and in order to comply with certain legislation and regulations. These expenditures include the costs of additional employees, with specific skills and experiences such as SEC reporting, higher insurance expense and internal controls as well as additional costs to outside service providers such as audit, tax, and legal fees.

See also Part II, Item 1A, Risk Factors below concerning the significant risks and uncertainties concerning the Company's business, operations, financial results and capital resources associated with the impact of the global coronavirus pandemic.

### **Off-Balance Sheet Arrangements**

During the period presented, we did not have any material off balance sheet arrangements, nor do we have any relationships with unconsolidated entities or financial partnerships, such as entries often referred to as structured finance or special purpose entities.

### **Item 3. Quantitative and Qualitative Disclosures about Market Risk**

Prior to July 15, 2019, our exposure to market risk due to changes in interest rates related primarily to the increase or decrease in the amount of interest expense from fluctuations in one-month LIBOR associated with our debt facility. For each 1% increase in one-month LIBOR in excess of the floor of 2%, our annual interest expense would have increased by approximately \$500,000. However, our Senior Secured Notes carry a 12.5% fixed interest rate per annum, thereby eliminating market risk due to changes in interest rates. Our cash and cash equivalents are maintained in FDIC protected accounts with no exposure to material changes in interest rates. At March 31, 2020, our interest rate on deposited cash was 0.35%. We do not purchase, sell or hold derivatives or other market risk sensitive instruments to hedge interest rate risk or for trading purposes. Further, we do not invest in any common stock or debt instruments that have been affected by the global COVID-19 outbreak which has resulted in material market movements during the quarter ended March 31, 2020.

Our accounts receivables are concentrated predominantly with Indivior. With the recent launch of Sympazan, our concentration with three large national wholesalers of pharmaceutical products is not significant presently but may become so in future periods should Sympazan sales increase and should other pipeline products become approved by the FDA and become distributed through these three regional, or other, wholesalers. In the event of non-performance or non-payment by either Indivior or the wholesalers, there may be a material adverse impact on our financial condition, results of operations or net cash flow.

### **Item 4. Controls and Procedures.**

#### *Management's Evaluation of our Disclosure Controls and Procedures*

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Securities Exchange Act of 1934, as amended (the "Exchange Act") is (1) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and (2) accumulated and communicated to our management, including to our principal executive officer and principal financial officer, to allow timely decisions regarding required disclosure.

As of March 31, 2020, our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(b) and 13a-15(e) under the Exchange Act). Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our principal executive officer and principal financial officer have concluded based upon the evaluation described above that, as of March 31, 2020, our disclosure controls and procedures were effective at the reasonable assurance level.

### *Internal Control Over Financial Reporting*

There were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) and 15d-15(f) under the Exchange Act), identified in connection with the evaluation of such internal control that occurred during our last fiscal quarter, that have materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## **PART II – OTHER INFORMATION**

### **Item 1. Legal Proceedings**

From time to time, we have been and may again become involved in legal proceedings arising in the course of our business.

### ***Patent-Related Litigation***

Beginning in August 2013, we were informed of abbreviated new drug application (“ANDA”) filings in the United States by Watson Laboratories, Inc. (now Actavis Laboratories, Inc., or “Actavis”), Par Pharmaceutical, Inc. (“Par”), Alvogen Pine Brook, Inc. (“Alvogen”), Teva Pharmaceuticals USA, Inc. (“Teva”), Sandoz Inc. (“Sandoz”), and Mylan Technologies Inc. (“Mylan”), for the approval by the FDA of generic versions of Suboxone Sublingual Film in the United States. We filed patent infringement lawsuits against all six generic companies in the United States District Court for the District of Delaware (the “Delaware District Court”). After the commencement of the ANDA patent litigation against Teva, Dr. Reddy’s Laboratories (“DRL”) acquired the ANDA filings for Teva’s buprenorphine and naloxone sublingual film that are at issue in these trials.

Of these, cases against three of the six generic companies have been resolved.

- *Mylan* and *Sandoz* settled without a trial. *Sandoz* withdrew all challenges and became the distributor of the authorized generic products.
- All cases against *Par* were resolved pursuant to a May 2018 settlement agreement between the Company, Indivior, and *Par* and certain of its affiliates.
- *Actavis* was found to infringe Patent No. 6,603,514, or the ‘514 patent, and cannot enter the market until the expiration of the patent in 2024, and the United States Court of Appeals for the Third Circuit (“Federal Circuit”) affirmed that ruling on July 12, 2019.
- *DRL* and *Alvogen* were found not to infringe under a different claim construction analysis, and the Federal Circuit affirmed that ruling on July 12, 2019. *Teva* has agreed to be bound by all DRL adjudications.

Subsequent to the above, all potential generic competitors without a settlement agreement were also sued for infringement of two additional new patents that contain new claims not adjudicated in the original Delaware District Court case against DRL and Alvogen. On July 12, 2019, the Federal Circuit affirmed the decisions from the previously decided cases. The remaining case against Actavis was dismissed in light of the infringement ruling above, which prevents Actavis from entering the market until 2024. The case(s) against the remaining defendants regarding the additional asserted patents have not been finally resolved. A *Markman* hearing in the cases against Dr. Reddy’s and Alvogen, which is pending in the United States District Court for the District of New Jersey (the “New Jersey District Court”), was held on October 17, 2019. On November 5, 2019, District Judge McNulty of the New Jersey District Court issued a *Markman* opinion construing the disputed terms of the asserted patents. On January 9, 2020, the New Jersey District Court entered a stipulated order of non-infringement of one of the patents, Patent No. 9,931,305, or the ‘305 patent, based on the Federal Circuit Court’s claim construction ruling, and we and Indivior preserved our rights to appeal the claim construction ruling. On November 19, 2019, Magistrate Judge Waldor of the New Jersey District Court issued an order granting DRL and Alvogen’s requests to file amended answers to add antitrust counterclaims against us and Indivior. We and Indivior appealed the Magistrate Judge’s decision to District Judge McNulty on December 4, 2019, and DRL and Alvogen opposed the appeal. The parties are awaiting further action from the New Jersey District Court on the appeal. On January 17, 2020, we filed a motion to dismiss DRL’s and Alvogen’s antitrust counterclaims for failure to state a claim and DRL and Alvogen opposed the motion. The parties are awaiting further action from the New Jersey District Court on the motion to dismiss. No trial date has been set in those cases. We are not able to determine or predict the ultimate outcome of this proceeding or provide a reasonable estimate or range of estimates of the possible outcomes or losses, is any, in this matter.

On February 19, 2019, the Federal Circuit issued its mandate reversing the District of New Jersey’s preliminary injunction against Dr. Reddy’s. Following issuance of the mandate, the District of New Jersey vacated preliminary injunctions against both Dr. Reddy’s and Alvogen. Dr. Reddy’s, Alvogen, and Mylan all launched generic versions of Suboxone Sublingual Film, and the launches by Dr. Reddy’s and Alvogen are “at risk” because the products are the subject of the ongoing patent infringement litigations.

On March 22, 2019, we and Indivior brought suit against Aveva Drug Delivery Systems, Inc., Apotex Corp., and Apotex Inc. in the United States District Court for the Southern District of Florida (the “Southern District of Florida Court”) for infringement of the Company’s U.S. Patents Nos. 8,017,150, 9,687,454, the ’514 patent and the ’305 patent, seeking an injunction and potential monetary damages. Following a negotiated settlement between all parties, on December 3, 2019, the parties submitted a Notice of Settlement and a Joint Motion to Approve Consent Judgment. The Southern District of Florida Court entered an order dismissing the suit on December 18, 2019.

We are also seeking to enforce our patent rights in multiple cases against BioDelivery Sciences International, Inc. (“BDSI”). Three cases are currently pending but stayed in the U.S. District Court for the Eastern District of North Carolina (the “Eastern District of North Carolina Court”):

- The first, a declaratory judgment action brought by BDSI against Indivior and Aquestive, seeks declarations of invalidity and non-infringement of U.S. Patents Nos. 7,897,080, 8,652,378 and 8,475,832. This case is stayed pending final resolution of the above-mentioned appeals on related patents.
- The second was filed by us and Indivior related to BDSI’s infringing Bunavail product, and alleges infringement of our patent, U.S. Patent No. 8,765,167, or the ’167 patent, and seeks an injunction and potential monetary damages. Shortly after the case was filed, BDSI filed four (4) IPR’s challenging the asserted ’167 patent. On March 24, 2016, the United States Patent Trial and Appeal Board (PTAB), issued a final written decision finding that all claims of the ’167 patent were valid. The case was stayed in May 2016 pending the final determination of the appeals on those decisions. Following the PTAB’s February 7, 2019 decisions on remand denying institution, we and Indivior submitted a notice to the Court on February 15, 2019 notifying the Court that the stay should be lifted as result of the PTAB’s decisions. We are awaiting further action from the Court.
- On January 13, 2017, we also sued BDSI asserting infringement of the ’167 patent by BDSI’s Belbuca product and seeking an injunction and potential monetary damages. On August 7, 2019, the Eastern District of North Carolina Court granted BDSI’s motion to dismiss the Complaint without prejudice and denied BDSI’s motion to stay as moot. On November 11, 2019, we filed a new Complaint against BDSI in the Eastern District of North Carolina Court. On November 27, 2019, BDSI filed a motion to stay the case pending BDSI’s appeal of the PTAB’s remand decisions, and we opposed the motion. The Eastern District of North Carolina Court denied BDSI’s motion to stay on April 1, 2020. BDSI’s appeal of the PTAB’s remand decisions to the United States Court of Appeals for the Fourth Circuit (the “Federal Fourth Circuit Court”) was docketed on March 13, 2019, and on March 20, 2019, we moved to dismiss the appeal for lack of jurisdiction. On August 29, 2019, the Federal Fourth Circuit Court granted the motion to dismiss BDSI’s appeal. On September 30, 2019, BDSI filed a petition for rehearing in the Federal Fourth Circuit Court *en banc*, which we opposed. The Federal Fourth Circuit Court denied BDSI’s petition for rehearing *en banc* on January 13, 2020. After the Federal Fourth Circuit Court denied BDSI’s petition, on January 13, 2020, BDSI filed with the Eastern District of North Carolina Court a motion to dismiss the Complaint, and we opposed the motion on February 2, 2020. The Eastern District of North Carolina Court denied BDSI’s motion to dismiss on April 1, 2020. On April 16, 2020, BDSI filed an Answer to the Complaint, including counterclaims for non-infringement, invalidity, and unenforceability of the ’167 patent. Our response to BDSI’s counterclaims is due May 7, 2020.

### **Antitrust Litigation**

On September 22, 2016, forty-one states and the District of Columbia, or the States, brought suit against Indivior and us in the U.S. District Court for the Eastern District of Pennsylvania, alleging violations of federal and state antitrust statutes and state unfair trade and consumer protection laws relating to Indivior’s launch of Suboxone Sublingual Film in 2010 and seeking an injunction, civil penalties, and disgorgement. After filing the suit, the case was consolidated for pre-trial purposes with the *In re Suboxone (Buprenorphine Hydrochloride and Naloxone) Antitrust Litigation*, MDL No. 2445, or the Suboxone MDL, a multidistrict litigation relating to putative class actions on behalf of various private plaintiffs against Indivior relating to its launch of Suboxone Sublingual Film. While we were not named as a defendant in the original Suboxone MDL cases, the action brought by the States alleges that we participated in an antitrust conspiracy with Indivior in connection with Indivior’s launch of Suboxone Sublingual Film and engaged in related conduct in violation of federal and state antitrust law. We moved to dismiss the States’ conspiracy claims, but by order dated October 30, 2017, the Court denied our motion to dismiss. We filed an answer denying the States’ claims on November 20, 2017. The fact discovery period closed July 27, 2018, but the parties agreed to conduct certain fact depositions in August 2018. The expert discovery phase closed May 30, 2019, but additional reports and depositions were conducted through August 1, 2019. *Daubert* briefing is ongoing. The remainder of the case schedule, including summary judgment briefing, is stayed pending resolution of Indivior’s appeal of the District Court’s class certification ruling in a co-pending multi-district litigation to which we are not a party. We are not able to determine or predict the ultimate outcome of this proceeding or provide a reasonable estimate, or range of estimate, of the possible outcome or loss, if any, in this matter.

## California Complaint

On December 5, 2019, Neurelis Inc. (“Neurelis”) filed a complaint against Aquestive in the Superior Court of California, County of San Diego alleging Unfair Competition, Defamation, and Malicious Prosecution related to the Company’s pursuit of FDA approval for Libervant™. Neurelis filed a First Amended Complaint on December 9, 2019, alleging the same three causes of action. The Company filed a Motion to Strike Neurelis’s Complaint under California’s anti-SLAPP (“strategic lawsuit against public participation”) statute on January 31, 2020, which Neurelis is expected to oppose. Neurelis filed a motion for leave to file a Supplemental Complaint on February 5, 2020, which we will oppose. A hearing on our anti-SLAPP motion and Neurelis’s motion for leave was scheduled for April 24, 2020 but was postponed as a result of court closures in San Diego County, California resulting from the COVID-19 pandemic. The parties are awaiting further action from the court regarding a new hearing date. We are not able to determine or predict the ultimate outcome of this proceeding or provide a reasonable estimate, or range of estimate, of the possible outcome or loss, if any, in this matter.

### Item 1A. Risk Factors

In light of recent developments relating to the COVID-19 global pandemic, the Company is supplementing the risk factors previously disclosed in Item 1A of its Annual Report on Form 10-K for the year ended December 31, 2019, as filed with the Securities and Exchange Commission on March 11, 2020, to include the following risk factor under the heading “Risks Related to our Business Operations and Industry”:

#### ***Our business may be adversely affected by the ongoing coronavirus pandemic.***

Beginning in late 2019, the outbreak of a novel strain of a virus named SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2), or coronavirus, which causes coronavirus disease 2019, or COVID-19, has evolved into a global pandemic. Depending upon the length and severity of the pandemic, which cannot be predicted, we may experience disruptions that could materiality and adversely impact our business including:

- Various aspects of our clinical trials, including delays or difficulties in enrolling patients in our clinical trials, in clinical trial site initiation, and in recruiting clinical site investigators and clinical site staff; increased rates of patients withdrawing from clinical trials; diversion of healthcare resources away from the conduct of clinical trials; interruption of key clinical trial activities such as clinical trials site data monitoring due to limitations on travel imposed or recommended by federal or state governments; impact on employees and others or interruption of clinical trial visits or study procedures which may impact the integrity of subject data and clinical study endpoints; and interruption or delays in the operations of the U.S. Food and Drug Administration, FDA, and comparable foreign regulatory agencies, which may impact regulatory review and approval timelines.
- If any third-party in our supply chain for any materials, including active pharmaceutical ingredients and other raw materials supply, which we need for our product candidates for our clinical trials and for the approved products we manufacture and distribute, are adversely impacted by restrictions resulting from the coronavirus pandemic, including staffing shortages, production slowdowns, or disruptions in freight and other transportation services and delivery distribution systems, our supply chain may be disrupted, limiting our ability to manufacture our product candidates for our clinical trials, conduct our research, development and clinical operations, and manufacture, distribute and sell our approved products.
- We have closed our business office and requested most of our colleagues located there to work from home, restricted on-site staff generally to those colleagues who must perform essential activities on-site and limited the number of staff in our research and development laboratory. Our increased reliance on colleagues and other third parties on whom we rely working from home or having health issues may negatively impact productivity and our commercialization activities for our existing approved products and commercial launch activities for any new approved product, or disrupt, delay, or otherwise adversely impact our business. In addition, this could increase our cybersecurity risk, create data accessibility concerns, and make us more susceptible to communication disruptions, any of which could adversely impact our business operations. Our colleagues conducting research and development activities may not be able to access our laboratory or manufacturing facilities for an extended period of time as a result of the closure of our facilities and the possibility of further governmental restrictions. As a result, this could delay timely completion of pre-clinical activities, including completing Investigational New Drug (IND)/Clinical Trial Application (CTA) enabling studies or our ability to select future development candidates, and initiation of clinical or other of our development programs and production and delivery of our products.



- The FDA and comparable foreign regulatory agencies may experience disruptions, have slower response times or be under-resourced to continue to monitor our clinical trials or to conduct required activities and review of our product candidates seeking regulatory review and such disruptions could materially affect the development, timing and approval of our product candidates.
- The coronavirus pandemic may impact the requirements of our customers and growth of our approved products. For example, Indivior, our significant customer for Suboxone, recently announced that it anticipated coronavirus impact on its product sales. We cannot predict the likely potential adverse impact of the coronavirus pandemic on the requirements for orders of our approved products Suboxone and Sympazan. We also could experience extended customer payment cycles.
- As a result of market volatility caused by continued effects of the coronavirus affecting the global economy, we may face difficulties raising capital through sales of our common stock or other securities. In addition, a recession, depression or other sustained adverse market event could materially and adversely affect the financial markets, our business, the value of our common stock and our ability to obtain on favorable terms, or at all, equity or debt financing or the monetization of our royalty streams.

The coronavirus pandemic continues to rapidly evolve. The ultimate impact of the coronavirus pandemic on us is highly uncertain and subject to change and will depend on future developments, which cannot be accurately predicted. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, our research programs, the manufacturing, marketing, distribution and sale of our approved products, the healthcare system or the global economy. Given the uncertainties, the Company is unable to provide assurance that operations can be maintained as planned prior to the COVID-19 pandemic.

Please also refer to the complete Item 1A of the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 11, 2020 for additional risks and uncertainties facing the Company, any of which risks and uncertainties may be further heightened by the coronavirus pandemic and have a material adverse effect on the Company's business prospects, financial condition, results of operations, liquidity and available capital resources.

**Item 2. Unregistered Sales of Equity Securities and Use of Proceeds**

None.

**Item 3. Defaults Upon Senior Securities**

None.

**Item 4. Mine Safety Disclosures**

Not applicable.

**Item 5. Other Information**

None.

**Item 6. Exhibits**

The exhibits listed below are filed or furnished as part of this report.

<b>Number</b>	<b>Description</b>
<a href="#">10.1*</a>	First Amendment to License Agreement, effective as of March 16,2020, by and between Aquestive Therapeutics, Inc, and Sunovion Pharmaceuticals Inc. (formerly, Cynapsus Therapeutics, Inc.) (filed as Exhibit 10.1 to the Current Report on Form 10-K and to the Current Report on Form 8-K of the Company filed on March 20, 2020 and incorporated by reference herein).
<a href="#">31.1</a>	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a), as amended, under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).
<a href="#">31.2</a>	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a), as amended, under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).
<a href="#">32.1</a>	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith).
<a href="#">32.2</a>	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith).
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

\*Portions of this exhibit have been omitted pursuant to Rule 601(b)(10) of Regulation S-K. The omitted information is not material and would likely cause competitive harm to the registrant if publicly disclosed.

## SIGNATURES

Pursuant to the requirements of the Securities Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in the County of Somerset, State of New Jersey.

Aquestive Therapeutics, Inc.  
(REGISTRANT)

Date: May 5, 2020

/s/ Keith J. Kendall

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Keith J. Kendall  
*President and Chief Executive Officer*  
*(Principal Executive Officer)*

Date: May 5, 2020

/s/ John T. Maxwell

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John T. Maxwell  
*Chief Financial Officer*  
*(Principal Financial Officer)*

**Certification of Principal Executive Officer of Aquestive Therapeutics, Inc.  
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, Keith J. Kendall, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Aquestive Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the consolidated financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, consolidated results of operations and consolidated cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: May 5, 2020

/s/ KEITH J. KENDALL

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Keith J. Kendall  
*President and Chief Executive Officer*  
*(Principal Executive Officer)*

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**Certification of Principal Financial and Accounting Officer of Aquestive Therapeutics, Inc.  
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, John T. Maxwell, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Aquestive Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the consolidated financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, consolidated results of operations and consolidated cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: May 5, 2020

/s/ JOHN T. MAXWELL  
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John T. Maxwell  
Chief Financial Officer  
(Principal Financial Officer)

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**Certification of Principal Executive Officer  
Pursuant to 18 U.S.C. Section 1350, as Adopted  
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002**

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), I, Keith J. Kendall, President and Chief Executive Officer of Aquestive Therapeutics, Inc. (the “Company”), hereby certify that, to the best of my knowledge:

1. The Company’s Quarterly Report on Form 10-Q for the period ended March 31, 2020, to which this Certification is attached as Exhibit 32.1 (the “Quarterly Report”), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and
2. The information contained in the Quarterly Report fairly presents, in all material respects, the financial condition of the Company at the end of the period covered by the Quarterly Report and the results of operations of the Company for the period covered by the Quarterly Report.

Dated: May 5, 2020

/s/ KEITH J. KENDALL

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Keith J. Kendall  
*President and Chief Executive Officer*  
*(Principal Executive Officer)*

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Aquestive Therapeutics, Inc. under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Quarterly Report), irrespective of any general incorporation language contained in such filing.

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**Certification of Principal Financial and Accounting Officer  
Pursuant to 18 U.S.C. Section 1350, as Adopted  
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002**

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), I, John T. Maxwell, Chief Financial Officer of Aquestive Therapeutics, Inc. (the “Company”), hereby certify that, to the best of my knowledge:

1. The Company’s Quarterly Report on Form 10-Q for the period-ended March 31, 2020, to which this Certification is attached as Exhibit 32.2 (the “Quarterly Report”), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and
2. The information contained in the Quarterly Report fairly presents, in all material respects, the financial condition of the Company at the end of the period covered by the Quarterly Report and the results of operations of the Company for the period covered by the Quarterly Report.

Dated: May 5, 2020

/s/ JOHN T. MAXWELL

\_\_\_\_\_  
John T. Maxwell  
Chief Financial Officer  
(Principal Financial Officer)

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Aquestive Therapeutics, Inc. under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Quarterly Report), irrespective of any general incorporation language contained in such filing.

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